federal register

TUESDAY, OCTOBER 4, 1977
PART VI

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

■

IDENTIFICATION, CLASSIFICATION AND REGULATION OF TOXIC SUBSTANCES POSING A POTENTIAL OCCUPATIONAL CARCINOGENIC RISK

[4510–26]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1990]

IDENTIFICATION, CLASSIFICATION AND REGULATION OF TOXIC SUBSTANCES POSING A POTENTIAL OCCUPATIONAL CARCINOGENIC RISK

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Proposed rule and notice of hearing.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes a new general regulation concerning the identification, classification and regulation of toxic substances in American workplaces that may pose a carcinogenic risk to workers.[1] This proposal is necessary to allow OSHA to deal in a comprehensive way with the important problem of worker exposure to many toxic substances which may be potential or confirmed occupational carcinogens. This broad rulemaking proceeding is intended to establish: new procedures and a regulatory framework for regulating exposures to potential occupational carcinogens; OSHA's scientifically based policies concerning the identification and classification of potential occupational carcinogens; and three model standards for use in specific rulemakings involving such substances. The three proposed model standards incorporate OSHA's views concerning which protective provisions are generally the most appropriate to protect employees permanently against exposure to categories of toxic substances, as defined, and, in the model emergency temporary standard, which protective provisions are necessary to protect employees from the danger of cancer and which can be instituted immediately. Once promulgated in this rulemaking therefore, these proposed procedures, identification and classification criteria, and, as qualified above, the provisions of the model standards will be consistently applied and, as discussed in this proposal, foreclosed from reconsideration in future regulatory activity pursuant to these proposed regulations.

OSHA invites written comment on these proposed regulations and all of the issues raised or implicit therein. In that regard, OSHA has scheduled an informal public hearing for the receipt of oral testimony as well, as pointed out below.

DATES: Written comments concerning the proposed set of regulations and notices of intention to appear at the hearing must be postmarked on or before December 8, 1977; all materials and direct written testimony of witnesses which will be introduced into the hearing record by any party must be filed by no later than January 9, 1978; an informal hearing is scheduled to begin March 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. James Foster, Office of Public Affairs, OSHA, Third Street and Constitution Avenue NW., Room N3641, Washington, D.C. 20210 (202–523–8151).

SUPPLEMENTARY INFORMATION: Pursuant to sections 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1599, 29 U.S.C. 655, 657), the Secretary of Labor's Order 8–76 (41 FR 25059) and Title 29 of the Code of Federal Regulations (CFR), Part 1911, it is proposed to amend Title 29 of the CFR by adding at this time a new Part 1990, a subpart A to Part 1990 to deal with the identification, classification and regulation of toxic substances, in general, and a subpart B to Part 1990 to deal with the identification, classification and regulation of toxic substances, as defined, for which there is reported to be evidence of carcinogenic potential to humans. These regulations would apply to all employments in all industries covered by the Act, including general industry, construction, maritime and agriculture. OSHA requests the submission of written comments, data and arguments from interested persons on the variety of scientific, technical and procedural issues addressed or implicit in this proposal. In addition, an informal hearing has been scheduled to provide an opportunity for presentation of evidence concerning the issues and to facilitate the conduct of this rulemaking.

This proposed set of regulations attempts to deal with one of the most important issues OSHA faces, namely the exposure of workers to toxic substances which may be potential or confirmed occupational carcinogens. At the outset, OSHA recognizes that some 1,500 to 2,000 agents have been identified by the National Institute for Occupational Safety and Health (NIOSH) as being "suspect carcinogens" (*Suspected Carcinogens*, HEW Publication No. (NIOSH) 77–149, December, 1976). By definition, this means that NIOSH has found some scientific evidence, of varying degrees of quality and quantity, identifying those substances as having potential carcinogenic activity, based on observations in human populations or on results from experimentation with laboratory test animals. Yet, OSHA has completed regulatory activity for only 17 of those substances since its creation on April 29, 1971. OSHA recognizes that in regulating occupational exposure to potential carcinogens, many gaps remain in our knowledge of cancer, its causes, prevention and cure. However, to wait for years to resolve these issues scientifically without some consistent and workable system for the regulation of toxic substances, for which there is evidence of a carcinogenic potential to humans, would be, we believe, inconsistent with OSHA's statutory obligations and unacceptable to all.

Thus, OSHA proposes an orderly and comprehensive set of regulations to identify, classify and regulate potential carcinogens in American workplaces. This action is based upon three basic propositions, namely:

1. That the term "carcinogen," although perhaps difficult to define as a matter of science, must be defined for purposes of overall regulatory activity.

2. That a toxic substance, determined as a carcinogen in a mammalian test animal system, as defined, is to be treated *as a policy matter* as posing a carcinogenic risk to humans.

3. That when OSHA is dealing with a toxic substance, identified as a carcinogen, as defined herein, the permissible exposure limits will be set as low as feasible. In cases where there are suitable substitutes that are found to be less hazardous to the worker, no occupational exposure to the toxic substance will be permitted. In other words, unless there is evidence submitted in this rulemaking sufficient to convince the Secretary of Labor that *this general policy* is incorrect namely, that there is presently no means to determine a safe exposure level to a carcinogen, the permissible exposure limits will be set as low as feasible or occupational exposure will not be permitted in certain cases, both determinations to be made in the individual rulemakings conducted pursuant to this subpart.

In short, utilizing best available and generally accepted scientific knowledge to establish the carcinogenicity of a substance, OSHA proposes, in general, to rely on evidence from human epidemiological studies, adequately designed and conducted animal studies, or both The degree of conclusiveness of such data may permit regulation of the toxic substance as a Category I toxic substance or a Category II toxic substance. This set of regulations also provides for the classification of toxic substances for which further development of data may be needed before any regulatory activity as to carcinogenicity is concerned (Category III Toxic Substances) or for toxic substances which OSHA believes are not found in American workplaces although the evidence shows that if they were, they would be classified pursuant to this subpart (Category IV Toxic Substances). The classifications of Category I and II toxic substances will require OSHA to initiate appropriate regulatory action, through the means of one or more of the three model standards, to control or eliminate exposure to the toxic substance, by way of engineering controls, work practices, respirators or simple housekeeping procedures. The content and format of these model standards, as pointed out below, are to be followed in subsequent rulemakings pursuant to this subpart, except where OSHA determines that unique properties of the toxic substance require deviations, additions or changes from the general requirements found in the model standards.

[1] Later additional subparts to this Part may be added to include other generic approaches to other toxic substances, such as, for example, those posing a potential occupational teratogenic or mutagenic risk.

OSHA recognizes that some of the scientific concepts underlying this rulemaking may still be subject to controversy. Most, however, are not new but have, in fact, been the basis for policy decisions made, after scientific debate, by OSHA and other governmental agencies in the past. For example, see the preambles to OSHA's carcinogen standard, applicable to 14 selected substances, 29 CFR 1910.1003–1910.1016 (39 FR 3758), *aff'd, Synthetic Organic Chemical Manufacturers Assn.* v. *Brennan* 503 F. 2d 1155 (3rd Cir., 1974); the vinyl chloride standard, 29 CFR 1910.1017 (39 FR 35892) *aff'd, The Society of the Plastic Industry* v. *OSHA*, 509 F. 2d 1301 (2nd Cir.) *cert. den.*, 421 U.S. 992 (1975); the inorganic arsenic proposal (40 FR 3392, 1975); the coke ovens emissions proposal (40 FR 32268, 1975) and final, 29 CFR 1910.1029 (41 FR 46742, 1976); the asbestos proposal (40 FR 47652, 1975); the beryllium proposal (40 FR 48814, 1975) and the benzene emergency temporary standard, 29 CFR 1910.1028 (42 FR 22516, 1977).

In addition to previous OSHA regulatory decisions, the United States Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare, the United States Consumer Product Safety Commission (CPSC) and other governmental agencies and bodies have made, or recommended, regulatory decisions concluding that substances pose carcinogenic risks to man, based primarily or solely upon evidence derived from studies conducted in laboratory animal populations. In particular, decisions made by EPA regarding the cancellation or suspension of certain chlorinated hydrocarbon pesticides involved extensive consideration of carcinogenicity based on laboratory animal data. See, for example: *In Re Stevens Industries, et al.*, (37 FR 13369, June 30, 1972), *aff'd, Environmental Defense Fund (EDF)* v. *EPA*, 489 F. 2d 1247 (D.C. Cir. 1973); *In Re Shell et. al.*, (39 FR 37265, Oct. 18, 1974), *aff'd, EDF* v. *EPA*, 510 F. 2d 1292 (D.C. Cir. 1975); and *In Re Velsicol et al.*, (41 FR 7552, 1976) *aff'd, EDF* v. *EPA*, 548 F. 2d 998 (D.C. Cir. 1976). And FDA, in its decision to order the elimination of chloroform from human drug and cosmetic products, relied explicitly on data supplied by National Cancer Institute (NCI) experiments showing chloroform to be carcinogenic in test animals (41 FR 15026–29, April 9, 1976 and 41 FR 26842–46, June 29, 1976).

OSHA expects that some may question the policy decisions inherent in this proposal as going too far, while others may contend that they do not go far enough. OSHA believes, however, that all concerned should approach these issues in a spirit of co-operation and candor—and with the recognition that policy determinations in a legal framework cannot be based solely upon scientific fact where often factual data are incomplete. But, insofar as the central issue of whether exposure to carcinogens should be regulated, we believe that the time has come to say that at least this issue has been resolved. In that regard, we agree with the scientific blue ribbon Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens of NCI, when it reported over seven (7) years ago in 1970 to the Surgeon General of the United States that:

> An effective program to protect man from the mass of environmental cancer hazards is within reach. No more time should be allowed to pass before the recommendations set forth in this report are applied to reality. (p. 8)

Thus, we propose today a system for regulatory action which will assure, we believe, an internal consistency in regulating carcinogens and a speedy approach which will limit the size and scope of OSHA's rulemakings which have grown far beyond the ability of OSHA's staff to handle by the present case-by-case approach.

In proposing these regulations, OSHA is relying upon leading scientific evidence and opinions believed to reflect the research conclusions of individual cancer specialists and expert national and international cancer committees and agencies, as well as "experience gained under * * * other health and safety laws" (section 6(b)(5) of the Act). In such a task we recognize that we are operating "on the frontiers of scientific knowledge" *Industrial Union Department* v. *Hodgson*, 499 F. 2d 467, 474 (D.C. Cir. 1974) but with a "command to act" *Ethyl Corp.* v. *EPA*, 541 F. 2d 1, 28 (D.C. Cir. 1976). In this proposal, OSHA relies therefore, upon what it believes to be the best available and prudent evidence, interpretations and theories. Once these regulations are promulgated, OSHA is prepared to modify the views therein if new evidence or future scientific advances show we are in error.[2] But if we are, we hope that the error was in being too careful and overly protective of the worker, for the alternative would appear to be unacceptable to all concerned.

The Regulatory Dilemma

Any decision to regulate carcinogens is obviously complex. As the cancer rate increases, the causes elude us. Chemical or physical agents known or suspected to pose a risk of carcinogenicity in humans pose certain problems unique to the regulation of toxic materials in the workplace which are discussed below. And with the increasing number of environmental chemicals, the number of carcinogens also increases, together with the size and complexity of OSHA's rulemakings. However, in its six year history, OSHA has concluded only 4 rulemaking proceedings in the health area, namely the asbestos standard in 1972, the carcinogen standard in January 1974 (regulating 14 substances), the vinyl chloride standard in October 1974 and the coke oven emissions standard in October 1976.

A. Nature of the Disease

Cancer is a particularly dreaded and costly disease. As pointed out below, the natural course of its development is generally irreversible and autonomous. It is a disease generally characterized in its advanced stages by the aggressive growth of abnormal (immature) populations of cells. The early cellular events of the disease and the causative factors leading to initiation of the disease are poorly understood, although much progress has been made as a result of intensive research for several decades. There also is evidence—though not definitive—that at least some cancers may originate from a single transformed cell.

In any case, once the initial carcinogenic events have been triggered, the resulting aberrant cells are capable of progressing to stages where normal tissue is invaded, and cancerous cells are capable of spreading throughout the body, even though the agent or agents responsible for inducing the disease may be no longer present. Most body structures are composed of many different kinds of tissues made up of many different types of cells, any of which may give rise to cancer. A specific type of cancer draws its name generally from the type of cell affected. For example:

> Cancer of connective tissue, including bones, are generally called sarcomas.
>
> Cancer of epithelial cells that line the body's internal surfaces and cover the external surfaces (lung, breast, skin) are generally called carcinomas.
>
> Cancer of cells that compose the blood-forming system are generally called leukemias or lymphomas.

In most cases of cancer, unrestrained cell growth leads to the buildup of tumors which compress, invade, and/or destroy normal tissues; if untreated, these tumors usually lead to death. Like cells, there are different types of tumors, each of which may be distinct in its behavior. However, induced malignant tumors generally share some common characteristics such as a long latent period between initial exposure and manifestation of the disease, as pointed out below. Some other characteristics may also include a higher rate of cell growth than in the normal, surrounding tissues, failure to maintain the boundaries of normal tissue and organs, a microscopic appearance which suggests immature rather than mature tissues, and a tendency in the human to spread to parts of the body distant from the original site of the cancer. Not all these features however accompany every malignant tumor.

It also appears that the effects of continuous or occasional exposure to different carcinogenic agents may be cumulative or synergistic, as pointed out below. The development of cancer can take as long as five to forty years before the

[2] OSHA will not, however, modify its policies in actions taken subsequent to the promulgation of, and pursuant to, these regulations. Efforts in that regard should be addressed to the amendment of these regulations, as is warranted from time to time, as advances in science are made. OSHA, at no time, intends or believes that these regulations are scientifically inflexible or fail to recognize future scientific advances that may occur. OSHA will encourage petitions for amendments to these regulations, including the model standards, as conditions so warrant.

disease progresses to the point where detection is possible. Thus, cancer seen today may be due to exposure occurring as little as five or as many as forty or more years ago as pointed out below.

B. THE INCREASE IN CANCER AND ITS MASSIVE ECONOMIC, SOCIAL AND EMOTIONAL IMPACT

Only a few generations ago, human life expectancy was less than 40 years. Today, however, human life expectancy and general health conditions prevailing in developed countries such as the United States reflect a striking—and comparatively recent—improvement over those that characterized most of man's long history.

Throughout the 19th century, the prime life limiting factor in this country was infectious disease. Since 1900 however, public health measures and medicine have made remarkable contributions to human longevity in the United States. A man born in Massachusetts in 1850 had a life expectancy of 38.3 years; a woman, of 40.5 years. As the decades passed, life expectancy at birth inched upward—by 1900 a man could expect to live to 46 years and a woman to nearly 50. (U.S. Bureau of the Census, *Historical Statistics of the United States, Colonial Times to 1957* (Washington, D.C.: Government Printing Office, (1960), Series B76–100.) Today, such expectancy is much greater with rates approaching 80 years of age.

A comparison of leading causes of death in 1900 with those in 1960 reveals a noteworthy shift in disease patterns. At the turn of the century, infectious diseases—pneumonia, influenza, tuberculosis, gastroenteritis and poliomyelitis—were the leading killers, accounting for over 31 percent of all deaths. Owing to such medical advances as the development of immunization techniques and antibiotics, tuberculosis and gastroenteritis are no longer significant causes of death in the United States; diphtheria, typhoid fever and poliomyelitis have been nearly eliminated, and even influenza and pneumonia have declined in significance to one-seventh of their previous level.

On the other hand, heart disease and cancer—the fourth and eighth leading causes of death, respectively, in 1900 now lead the nation's list of killers. In 1900, these two diseases were responsible for only 12 percent of deaths; today, they account for more than one-half of U.S. mortality. Annual crude death rates from heart disease rose from 137.4 per 100,000 population in 1900 to 362 in 1970, while deaths from cancer rose in that same period of time from 64 per 100,000 population to 162.8 and to 171.5 in 1975. (President's Science Advisory Committee Panel on Chemicals, *Chemicals and Health* (Washington, D.C.: Government Printing Office, 1973), p. 152; U.S. Department of Health, Education, and Welfare, Public Health Service, *Facts of Life and Death*, DHEW Pub. No. (HRA) 74–1222 (Washington, D.C.; Government Printing Office, 1974), p. 31.)

Some increase in the number of cancer deaths may have been predicted on the basis of demographic factors, such as general aging of the population, and hence on the success of medicine in reducing the significance of infectious diseases. Another unquantifiable portion is undoubtedly traceable to improved reporting methods, i.e., some deaths from cancer in earlier times were mistakenly ascribed to other causes. Even after these factors have been taken into account, however, the death rate for cancer sharply exceeds predictions.

Cancer killed a reported 358,400 U.S. citizens in 1974—over 1,000 persons per day. Over one million are under treatment for the disease, and each year over 900,000 new cases are diagnosed. Of these, about one-third are skin cancers: Troublesome, sometimes painful, usually treatable, with an impact on life expectancy for about 2,000 humans per year; the other 600,000, however, are more serious and more of them are potentially fatal. The American Cancer Society now estimates that 25 percent of the United States' population will ultimately develop some form of cancer. (U.S. Department of Health, Education and Welfare, *Monthly Vital Statistics Report: Annual Summary for the United States*, Vol. 21, No. 13 (1975); U.S. Department of Health, Education and Welfare, National Institutes of Health, *National Cancer Program: The Strategic Plan*, DHEW Pub. No. (NIH) 74–569 (Washington, D.C.: Government Printing Office, 1973); American Cancer Society, *Cancer Facts and Figures* (New York, 1974).)

The economic and social impacts of cancer in the United States are massive and yet hard to estimate. Certainly the human anguish is. Those impacts, however, are very real. An estimated $1.8 billion per year is spent solely for hospital care of cancer patients. Additional costs, doctor bills, outpatient therapy, and other treatment-related fees, raise the direct annual expenditures for cancer well into the tens of billions of dollars. To these direct expenditures must be added indirect costs, such as the estimated 1.8 million work years lost annually to the national economy and to family income by unemployed or underemployed cancer victims. (U.S. Public Health Service, *Cancer Rates and Risks*, Pub. No. (NIH) 75–619 (Washington, D.C.; Government Printing Office, 1975, p. 3). One estimate cited by the General Accounting Office of the United States Congress (GAO) is that the annual cost of cancer is $15 billion, of which $3–5 billion is attributable to direct care and treatment and the remainder attributed to the loss of earning power and productivity (GAO, "Federal Efforts to Protect the Public From Cancer Causing Chemicals Are Not Very Effective", June 16, 1976, p. 1). This estimate is supported by a study prepared by NCI with information on the economic costs of cancer to the United States, and to individual patients' families in particular. See "The National Cancer Program, the Strategic Plan," January 1973 ed.

Cancer rates vary significantly through the United States. In general, however, States with high rates are the more industrialized States. It has long been known that densely populated and industrialized areas have higher death rates from many causes than nearby rural areas. Although urbanization and industrialization have been associated with heart disease, cancer of the respiratory and digestive systems, and many other diseases, the reasons for this association are not fully understood. This excess disease risk may be related to lifestyle (urban dwellers use more tobacco, for example), to occupation (working with toxic substances), to the environment of cities (air pollution and water pollution), or to other factors as yet unidentified, as well as combinations thereof.

C. THE RECOGNITION THAT THE DEVELOPMENT OF CANCER IS INFLUENCED BY ENVIRONMENTAL AND OCCUPATIONAL FACTORS

Most of the details of how and why cancers develop still elude scientists and physicians, so that the exact causative mechanisms of observed malignancies cannot be well defined. But a number of factors appear to be implicated, both separately and in combination, for many observed cancers.

Among the causes of cancer, those most prominent are believed to be traceable to environmental factors acting singularly or in conjunction with genetic or other susceptibilities. It should be remembered that the extensive exposure to cancer-causing environmental factors is relatively new in the history of man. Today, there is growing acceptance that 60 to 90 percent of all cancer may be related to environmental factors. (See, for example: World Health Organization, *Prevention of Cancer*, Technical Report Series 276 (Geneva, 1974); E. Boyland, "The Correlation of Experimental Carcinogenesis and Cancer in Man," *Progress in Experimental Tumor Research*, Vol. 11 (1969), pp. 222–34; S. S. Epstein, "Environmental Determinants of Human Cancer," *Cancer Research* Vol. 34 (1974), pp. 2425–35). The basis for the estimates largely derives from large community studies over extended periods of time, which have revealed wide geographical variations in the incidence of cancer of various organs. Specific examples include, among others, diet, the large component of cancer attributable to cigarette smoking, those resulting from exposures to chemicals in the workplace, and cancers from physical agents such as solar and ionizing radiation and asbestos and those caused by aflatoxins (a class of naturally occurring chemicals secreted by some molds on certain foodstuffs, such as peanuts).

The extent to which the observed incidence and rise in incidence of cancers are attributable to manmade chemicals cannot be estimated with any precision. The tragic effects, however, are evident. Recognition by cancer specialists that many, if not most, human cancers are influenced by environmental factors is of extraordinary significance to OSHA—it means that occupational cancers may be preventable if the causative agents

can be identified and human exposure to them eliminated or minimized.

Only some of these manmade agents have been identified. Unfortunately, our nation's capacity in the past to develop new chemical substances far exceeded its ability to determine their carcinogenic potential and, as pointed out, OSHA's ability to promulgate standards in any speedy fashion solely by way of the case-by-case approach. In the past 10 years, the production of synthetic organic chemicals has expanded by 255 percent; relatively few of the new compounds have been studied for their cancer-causing potential. Because of the typical latency period of 5–40 years for cancer in humans, we must assume that any increase in cancer which may have been initiated by recent industrial development is not yet observable. (Wilhelm C. Hueper, "Medicolegal Considerations of Occupational and Nonoccupational Environmental Cancers", Chapter 7 in *Lawyers Medical Cyclopedia;* Irving J. Selikoff and E. Cuyler Hammond, "Environmental Cancer in the Year 2000," presented at the Seventh National Cancer Conference, Los Angeles, Sept. 29, 1972).

D. MOST TOXIC MATERIALS APPEAR NOT TO BE CARCINOGENS EVEN AT HIGH DOSES

As additional studies are reported of the carcinogenicity of substances representing a wide range of chemical structures and used for a variety of purposes, there has been tendency for some to suspect that all chemicals are capable of causing cancer if administered to experimental animals at sufficiently high doses. This claim appears to be based on the belief that carcinogenesis is a nonspecific kind of biological process associated with any substance under the right conditions, namely that test animals, bred for their sensitivity to carcinogens, when fed maximum tolerated doses of a substance for their lifetime become very ill and may be more susceptible to carcinogenic effects. However, there is evidence that renders this suspicion very unlikely to be true.

A publication of the U.S. Department of Health, Education, and Welfare compiles and abstracts all substances tested for carcinogenic effects. ("Survey of Compounds Which Have Been Tested For Carinogenic Activity," Volumes I–*VII* (1947–1976)). Although these volumes are not intended to provide a critical evaluation of the data on each of the substances, only about 17 percent of over 6,000 were reported as showing tumorigenic effects and this in spite of the fact that most of the compounds were selected because of their suspicious nature.

In a study sponsored by NCI from 1965 to 1968 and performed by the Bionetics Research Laboratories under contracts PH 43–64–57 and PH 43–67–735, approximately 130 pesticide and industrial chemicals were tested for carcinogenic activity. Pesticide chemicals, of course, are known to possess high biological activity as demonstrated by their use as pesticides. In addition, the substances tested in the Bionetics study were selected on the basis of a number of criteria, among which were: (1) Published evidence of toxicity that suggested potential hazards to man and (2) the similarity between possible test substances and substances of known carcinogenic activity. Each substance was fed to both sexes of two strains of mice at a maximum tolerated dose determined at a young age [3] by continuous oral administration with both positive and negative controls for 18 months. Despite weighting in the choice of test substances, less than 10 percent of the substances tested definitely produced tumorigenic effects and most of the others gave no evidence of carcinogenicity. (J.R.M. Innes et al., "Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note." J. Natl. Cancer Inst. 42, 1101–14, 1969).)

Furthermore, it has been recognized for many years that the negative findings of carcinogenic bioassays are often not published and are even rejected for publication (Report of the Panel on Carcinogenicity, Int. Union Against Cancer, "Carcinogenicity Testing," edited by I. Berenblum, IUAC Geneva, 1969). Thus, the percentage of substances tested for carcinogenic activity and found positive may be even lower than present data indicate.

During the hearings to consider the intent of the Administrator of the U.S. Environmental Protection Agency to cancel the registration of pesticides aldrin and dieldrin, testimony was presented concerning this proposition. The then Associate Director for Carcinogenesis of the Division of Cancer Cause and Prevention at NCI, Dr. Umberto Saffiotti, testified:

> Not all chemicals can cause cancers, contrary to some ill-informed belief; in fact, only a relatively small proportion of the chemical species that have been studied are capable of such activity. The activity is dependent on a number of specific chemical and physical properties of the molecules, which are gradually brought to light. It can be expected that, when thousands of new environmental chemicals will be tested, only a few hundred, or maybe just a few dozen, will be found to be carcinogenic, and it will be possible to concentrate our preventive measures on those. (Exhibit 40 of the EPA Public Hearings concerning the cancellation of the pesticide registrations of Aldrin and Dieldrin, 1973, pp. 7–8).

Thus, the available evidence provides strong indication indeed that not all chemicals are capable of causing cancer and that only a small number of the total is so capable. This apparent fact has also been recognized by two Administrators of EPA. In the DDT cancellation proceeding. *In Re Stevens Industries, et al.*, EPA IFR Docket No. 63 et al., 37 FR 13369 (1972), *aff'd, EDF* v. *EPA*, 489 F. 2d 1247 (D.C. Cir. 1973), Administrator William D. Ruckelshaus stated:

> The 'everything is cancerous' argument fails because it ignores the fact that not all chemicals fed to animals in equally concentrated doses have produced the same tumorigenic results. (37 FR 13371)

Likewise, in the Aldrin and Dieldrin suspension proceeding, *In Re Shell Chemcial Co. et al.*, EPA FIFRA Docket No. 145, 39 FR 37265 (1974) *aff'd, EDF* v. *EPA*, 510 F. 2d 1292 (D.C. Cir. 1975), Administrator Russell E. Train stated:

> Carcinogenicity is a relatively rare phenomenon exhibited by only a few of the many hundreds of thousands of chemicals. (39 FR 37268)

And in ordering the suspension of the pesticides Heptachlor and Chlordane in *In Re Velsicol Chemical Co. et al.*, EPA FIFRA Docket No. 384, 41 FR 7572 (1976), *aff'd, EDF* v. *EPA*, 548 F. 2d 998 (D.C. Cir. 1976), Administrator Train stated:

> Finally, I have noted some tendency, not entirely absent from the record, to assert that any chemical, if fed in sufficiently large amounts, will cause cancer in test animals. This is not true. A study sponsored by the National Cancer Institute tested 140 pesticides and industrial chemicals in two strains of mice, and less than ten percent of these were found to be carcinogenic. (41 FR 7575)

E. LATENCY AND IRREVERSIBILITY OF EFFECT

Another very troubling problem to the regulation of chemical carcinogens is posed by two biological characteristics of cancer that *are* well-established and that distinguish it from other processes of chronic toxicity. These are the general irreversibility of effect and the generally long latent period between exposure to the carcinogen and manifestation of the effect, namely the tumor.

1. *Irreversibility.* The reasons underlying the irreversibility of effect are fundamental to the understanding of the mechanisms of chemical carcinogenesis. The effect under consideration is the induction of a critical change in the target cells which determines their subsequent growth as tumor cells. The specific molecular target of a carcinogen within a cell is not yet fully identified, although it is known that carcinogens can interact directly with the genetic material of the cells (DNA), as well as with other molecules that control cellular functions (RNA and proteins).[4]

Once a cell has been switched ("transformed") from its normal status to a neoplastic one, this cell can replicate and produce neoplastic daughter cells. Only a few initially transformed neoplastic cells may be sufficient to give rise to a growing tumor. There is experimental evidence that even a single cell can be transformed by chemicals to produce

[3] It should be noted that use of this maximum tolerated dosage was the basis for criticism by one member of the Mrak Commission's Technical Panel on Carcinogenicity as being less than the maximum tolerated dose once the animals reached maturity and therefore might mean that at higher dose levels, carcinogenic effects could have been observed for more substances. (Report of the Secretary's Commission on Pesticides and the Relationship to Environmental Health, U.S. Department of Health, Education, and Welfare, Nov. 1969, p. 483).

[4] For instance, see I. B. Weinstein, N. Yamaguchi, R. Gebert, and M. E. Kaighn, "Use of Epithelial Cell Cultures for Studies on the Mechanism of Transformation by Chemical Carcinogens," *In Vitro, 11*, 130–141 (1975).

a malignant tumor.[5] It is consistent with our knowledge of carcinogenesis that a relatively small number of molecules may be sufficient to initiate a neoplastic change in a target cell. Following such an initial event, exposure to the carcinogen is no longer required to maintain the initial alteration that leads ultimately to a cancer cell, which is then capable of autonomous growth. Thus a single biological event produced by a very small number of molecules of the carcinogen may be sufficient to initiate the irreversible development of a tumor. As the Ad Hoc NCI Committee's report to the Surgeon General stated in 1970:

> The effects of carcinogens on tissues appear irreversible. Exposure to small doses of a carcinogen over a period of time results in a summation or potentiation of effect. The fundamental characteristic which distinguishes the carcinogenic effect from other toxic effects is that the tissues affected do not seem to return to their normal condition. This summation of effects in time and the long interval (latent period) which passes after tumor induction before the tumor becomes clinically manifest demonstrate that cancer can develop in man and in animals long after the causative agent has been in contact and disappeared. (p. 2)

2. *Long latent period.* The other important characteristic of the carcinogenic effect is that it is a *delayed effect*, one where the manifestation (the appearance of a tumor) follows the causative exposure by a long period of time, called the latent period, during which the action of the carcinogen on the host, although already effected, cannot currently be detected. In man, as well as in experimental animals, the latent period of chemical carcinogens is often as long as a major portion of a lifetime. It has been found to be as long as 15, 20, 30 or more years in man, while it is usually from 1 to 2 years or even more in rodents, which live up to two or three years. In most cases the latent period for human carcinogenesis is 5 to 40 years. In case histories of human exposure to chemical carcinogens with such long latent periods, such as cigarette smoke or asbestos, conclusive epidemiological findings were not available until 20 or more years after the start of exposure, by which time large numbers of persons had been exposed and a substantial cancer epidemic had been caused. Thus, as pointed out below, the significance of the long latent period for chemical carcinogenesis is that *it is impractical and imprudent to wait for results of epidemiological studies in man;* prevention of chemical carcinogenesis in man requires identification of the carcinogens by experimentation in laboratory animals with a short lifetime and a correspondingly short latent period for tumor induction. As the Ad Hoc NCI Committee's report to the Surgeon General stated:

> It is, therefore, important to realize that incidences of cancer in man today reflect expcsure of 15 or more years ago; similarly, any increase of carcinogenic contaminants in man's environment today will reveal its carcinogenic effect some 15 or more years from now. For this reason, it is urgent that every effort be made to detect and control sources of carcinogenic contamination of the environment well before damaging effects become evident in man * * * Environmental cancer remains one of the major disease problems of modern man. (p. 2)

And, as Administrator Russell Train of EPA pointed out in *In Re Velsicol, supra:*

> * * * the latency periods for cancer inducing chemicals tend to be long (in the tens of years), so that what results there are from the study of human exposure are difficult to gather and may well appear too late to save people from an already widespread chemical to which they are unavoidably exposed. (41 FR 7575)

F. KNOWN HUMAN CARCINOGENS ARE ALSO CARCINOGENS IN ANIMALS

At least 28 chemical substances or mixtures are known to cause cancer in man; in most cases this knowledge is derived from epidemiological studies. With one or possibly two exceptions, all of these are known to cause cancer in experimental animals. In the text of a review published by Dr. U. Saffiotti:

> "Over one thousand chemical substances have been shown to be carcinogenic by tests in animals (although some of the 'positive' tests reported in the literature—particularly the older ones—are not quite satisfactory by present standards). Several individual chemicals or mixtures of chemicals have also been shown conclusively to be carcinogenic by direct observation in man (Table 1). With the exception of arsenic, still under experimental study, all the main products that were found to be carcinogenic by direct evidence in man have also been proven carcinogenic in animals. On the other hand, proof that a substance, which had been recognized as carcinogenic in animals, actually causes cancer in man would require in most cases extremely complex and lengthy epidemiologic studies. In many cases, it may be impossible to obtain such proof because of the complexity of controls that would be needed for a satisfactory demonstration. Therefore, the only prudent course of action at the present state of our knowledge is to assume that chemicals which are carcinogenic in animals could also be so in man, although the direct demonstration in man is lacking. (U. Saffiotti, "The laboratory approach to the identification of environmental carcinogens"; in Scholefield, P.G. (Ed.): *Proceedings of the Ninth Canadian Cancer Research Conference 1971, pp. 23–26; University of Toronto Press 1972.*)

In a report by a Committee of the National Research Council (Contemporary Pest Control Practices and Prospects, Vol. 1, 1975: "NRC Pest Control"), published data on 13 compounds known to also cause cancer in man are tabulated: 12 of them are known to also cause cancer in mice, rats, and/or hamsters (NRC Pest Control, pp. 67–73).

Notwithstanding the difficulty of identifying specific carcinogens affecting man, about a dozen agents are now recognized as human carcinogens. All of these but one are definitely carcinogenic in tests on laboratory animals, as indicated in Table 4. The only exception is arsenic, which is still under test on animals. It may be noted that the organs affected in man are not always the same as those that are found to develop tumors in laboratory animals, nor is the organ specifically the same in different species of rodents. Nevertheless, the evidence, based on a limited number of carcinogens, suggests that most agents that pose a carcinogenic threat to man will be carcinogenic in laboratory tests on animals. (NRC Pest Control, p. 66)

The NRC Committee also tabulated numerical data on the doses of these chemicals associated with increased cancer incidence (*ibid.*, pp. 75–81, Table 5). They found an approximate correspondence between the sensitivities of humans and rodents when they were compared on the basis of cumulative lifetime exposure:

> Thus, as a working hypothesis, in the absence of countervailing evidence for the specific agent in question, it appears reasonable to assume that the lifetime cancer incidence induced by chronic exposure in man can be approximated by the lifetime incidence induced by similar exposure in laboratory animals at the same total doses per body weight. (*Ibid.*, p. 82)

The reliance of EPA on animal test data, and other similar principles set forth herein, as indicating human carcinogenic potential has been judicially approved. For example, in referring, albeit, to an adjudicatory proceeding concerning the suspension of a pesticide, the United States Court of Appeals stated in *EDF* v. *EPA* (Velsicol) 548 F. 2d 998, 1006–07 (D.C. Cir. 1976):

> We start by rejecting Velsicol's argument that the 'cancer principles' EPA relied on in structuring its analysis of the mice and rat studies improperly biased the agency's open-minded consideration of the evidence. In brief form, the principles accept the use of animal test data to evaluate human cancer risks; consider a positive oncogenic effect in test animals as sufficient to characterize a pesticide as posing a cancer risk to man; recognize that negative results may be explained by the limited number and sensitivity of the test animals as compared to the general human population; note that there is no scientific basis for establishing a no-effect level for carcinogens; and view the finding of benign and malignant tumors as hazard to man given the increasing evidence that many 'benign' tumors can develop into cancer. The Agency's reliance on these principles did not come as a surprise to Velsicol; they were included in the Administrator's Notice of Intent to Suspend; and as recognized in *EDF* v. *EPA*, 167 U.S. App. D.C. at 77–78, 510 F. 2d at 1298–99, form part of the Agency's 'scientific expertise.' Velsicol was properly given an opportunity to put in evidence contesting those principles, but failed to demonstrate anything more than some scientific disagreement with respect to them. Velsicol's principal complaint—that mice are inappropriate test animals—was specifically rejected by the Administrator, citing statements by the National Academy of Sciences' Food Protection Committee, the World Health Organization, HEW's Commission on Pesticides and their Relationship Environmental Health, FDA Advisory Panel on Carcinogenesis, International Agency for Research on Cancer, and Director of the National Cancer Institute's Carcinogenesis Program. Unlike the failure to adduce critical methodology that we criticized in *International Harvester*, EPA's specific enunciation of its underlying analytic principles, derived from its experience in the area, yields meaningful notice and dialogue, enhances

[5] P. J. Fialkow, "The Origin and Development of Human Tumors Studied with Cell Markers", *New England Journal of Medicine* 291, 26–35 (1974); S. M. Gartler, "Utilization of Mosaic Systems in the Study of the Origin and Progression of Tumors," in: *J. German* (ed), Chromosomes and Cancer, pp. 317–352, (1973).

the administrative process and furthers reasoned agency decisionmaking" (omitting footnotes).

G. THE LEGAL MANDATE AND THE REGULATORY APPROACH

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every American employee over the period of his or her working lifetime. One means prescribed by Congress to achieve this goal is the mandate given to, and the concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Act provides specifically that:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of standards, and experience gained under this and other health and safety laws. (Section 6(b)(5)).

In setting standards pursuant to the Act, the Secretary is expressly required to consider the feasibility of the proposed standards. Senate Committee on Labor and Public Welfare, S. Rep. No. 91–1282, 91st Cong., 2d Sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology. *The Society of the Plastics Industry* v. *OSHA, supra* at 1309.

Where appropriate, the standards are required to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, appropriate medical examinations and training and education. Moreover, where a standard prescribes medical examinations or other tests, they must be made available at no cost to the employees (section 6(b)(7)). Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (section 8(c)).

Sections 2(b)(5), 2(b)(6), 6, 20, 21, 22, and 24 of the Act reflect Congress' recognition that conclusive medical or scientific evidence including causative factors, epidemiological studies or dose response data may not exist for many toxic materials or harmful physical agents. Nevertheless, Congress mandated that standards should not be postponed because definitive medical or scientific evidence is not currently available. Indeed, while final standards are based on the best available evidence, the legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Comm. On Education and Labor, H.R. Rep. No. 91–1291, 91st Cong., 2d Sess. 18 (1970).

This congressional judgment is supported by the Courts which have reviewed standards promulgated under the Act. In *Industrial Union Department, AFL–CIO* v. *Hodgson*, 499 F. 2d 467 (D.C. Cir. 1974), the United States Court of Appeals considered the Secretary of Labor's delegated mandate and power under the Act to protect the health of workers from exposure to asbestos. It stated (499 F. 2d at 474):

From extensive and often conflicting evidence, the Secretary in this case made numerous factual determinations. With respect to some of those questions, the evidence was such that the task consisted primarily of evaluating the data and drawing conclusions from it. The court can review that data in the record and determine whether it reflects substantial support for the Secretary's findings. But some of the questions involved in the promulgation of these Standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.[18]

This rationale was likewise applied in *The Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F. 2d 1301 (2d Cir.), *cert. den.* 421 U.S. 992 (1975), where the Second Circuit reviewed regulations limiting worker exposure to vinyl chloride. The Court stated at 1308:

As in Industrial Union Department, *AFL–CIO* v. *Hodgson, supra*, the ultimate facts here in dispute are on the frontiers of scientific knowledge, and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient. The Secretary, in extrapolating the MCA study's findings from mouse to man, has chosen to reduce the permissible level to the lowest detectable ones. We find no error in this respect.

And in *Ethyl Corp.* v. *EPA* 541 F. 2d 1 (D.C. Cir. 1976), the Court of Appeals affirmed the EPA Administrator's decision to limit lead in gasoline, based in large part upon the rationale of *IUD* v. *Hodgson, supra* and *SOCMA* v. *OSHA, supra*. The Court stated at pp. 24–28:

Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public health against gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a prescience that removes all doubt from their decisionmaking. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or nonexistent data base upon which to draw? Never before have massive quantities of asbestiform tailings been spewed into the water we drink. Never before have our industrial workers been occupationally exposed to vinyl chloride or to asbestos dust. Never before has the food we eat been permeated with DDT or the pesticides aldrin and dieldrin. And never before have hundreds of thousands of tons of lead emissions been disgorged annually into the air we breathe. Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes—and common sense—demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Undoubtedly, certainty is the scientific ideal—to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the leisurely and isolated scrutiny of an entire mechanism. Awaiting certainty will often allow for only reactive, not preventive, regulation. Petitioners suggest that anything less than certainty, that any speculation, is irresponsible. But when statutes seek to avoid environmental catastrophe, can preventive, albeit uncertain, decisions legitimately be so labeled? 541 F. 2d 1 at pp. 24–25, omitting footnotes.

* * * * *

That petitioners, and their scientists, find a basis to disagree is hardly surprising, since the results are still uncertain, and will be for some time. But if the statute accords the regulator flexibility to assess risks and make essentially legislative policy judgments, as we believe it does, preventive regulation based on conflicting and inconclusive evidence may be sustained. Recent cases have recognized this flexibility in similar situations [citing *IUD* v. *Hodgson*; *SOCMA* v. *OSHA*, supra; and *Reserve Mining Co.* v. *EPA* 514 F. 2d 492 (8th Cir. 1975) (*en banc*)] 541 F. 2d 1 at 26.

* * * * *

Where a statute is precautionary in nature,[57] the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand vigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served. 541 F. 2d 1 at 28.

And finally, in *Certified Color Manufacturers Ass'n* v. *Mathews* 543 F. 2d 284 (D.C. Cir. 1976), the Commissioner of FDA had terminated provisional approval of the color additive "Red Dye No. 2" because of evidence that it caused cancer in rats. In affirming that action, the Court stated at 297–98:

Courts have traditionally recognized a special judicial interest in protecting the pub-

[18] Where existing methodology or research in a new area of regulations is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information, Permian Basin Area Rate Cases, 390 US 747, 811, 88 S. Ct. 1344, 20 L. Ed. 2d 312 (1968).

[57] Or, as with OSHA, mandatory in its command to act. *See* note 56 *supra*.

lic health, particularly where 'the matter involved is as sensitive and frightladen as cancer'. Where the harm envisoned is cancer, courts have recognized the need for action based upon lower proof than otherwise applicable (footnotes omitted).

This proposal marks a departure from OSHA's usual pattern of a substance-by-substance approach in setting health standards concerning exposures to potential occupational carcinogens. One obvious result of OSHA's current case-by-case approach to the regulation of carcinogens has been the relitigation of certain issues in each and every rulemaking. This taxes witnesses who have in the past been willing to testify in prior rulemakings. In addition, the system hardly guarantees a continuity of approach in every case, whether it be within the Agency or within the Courts. And finally, the manpower resources of OSHA are exceeded using the present approach. See, for example, the affidavits of the chief legal advisor and the chief of the health standards division filed in an action brought to compel the issuance of a cotton dust standard (*Textile Workers Union of America, et. al.* v. *Wm. J. Usery, Jr., et. al.*, Civil Action No. 75–2157 (D.D.C. ——, 1975)). It is OSHA's belief that if this proposal or something similar is not promulgated, with present resources the output of standards to protect American workers from carcinogens will never be adequate and may collapse by means of the futility of the effort. Indeed, to follow the present system and procedure for each and every individual substance and hazard would be, we contend, beyond the abilities of any agency, no matter how large a staff it may have.

The vinyl chloride standard (29 CFR 1910.1017) provides a striking example of the effort which has been required for standard promulgation, under optimum circumstances, pursuant to the *de novo* case-by-case approach. That standard, developed on a top priority basis with resources borrowed from other ongoing projects, took the full statutory six months from the issuance of the emergency temporary standard, through the required hearings and the adequate review of the record, to publish a final rule. And that time does not include the time and manpower devoted to the earlier fact-finding hearing and the necessary preparation of the emergency temporary standard and preamble themselves Moreover, that time does not include the resources that were required to defend the final standard in the appellate courts. The ETS itself was not contested.

The vinyl chloride rulemaking proceedings concerned a substance which undisputedly was a human carcinogen. Yet, controversy raged during the hearing concerning the precise level of exposure which posed a hazard, whether a "safe" exposure level existed, whether animal data could be prudently extrapolated to man in quantitative terms and the appropriateness of the regulatory requirements. The comments and testimony concerning these issues were discussed in a significant part of the more than 600 written comments, 200 written and oral hearing submissions, the hearings, and the 4,000 page record.

Notwithstanding the bulk and comprehensiveness of the record, OSHA finally determined that the record did not provide definitive answers to these questions. The Agency declared, "[w]e cannot wait until indisputable answers to these questions are available, because lives of employees are at stake," (39 FR 35892).

Moreover, certain issues predictably and inevitably reoccur in other proceedings concerning highly toxic and carcinogenic substances, such as arsenic, coke oven emissions, benzene and beryllium. Yet, the determinations on these issues have been made by the Agency as a matter of "policy", not necessarily with complete factual certainty at the time of that determination. These determinations have been upheld as policy matters. For example, OSHA's determination in the preamble to the final standard regulating exposure to one of the 14 carcinogens, (ethyleneimine, EI), that carcinogencity in animals should be treated as posing a carcinogenic threat to humans, was characterized by the United States Court of Appeals for the Third Circuit as "not really a factual matter." Rather, the Court stated that, the determination "is in the nature of a recommendation for prudent legislative action," i.e., a policy decision. *SOCMA* v. *Brennan*, 503 F. 2d 1155, 1159 (3d Cir., 1974).

To dedicate substantial (and unavailable) resources to the rehearing, and record resubstantiation in each and every rulemaking, of these kinds of policy issues is truly nonproductive if we are honestly concerned about the health of workers and, possibly, the future of mankind.

OSHA therefore, like other administrative agencies in the past, has determined that it is necessary at this time, to the fulfillment of its statutory objectives, to reshape the size and content of its rulemaking proceedings at least insofar as potential carcinogens are concerned. This proposed set of regulations incorporates policy determinations concerning how and when chemical or physical substances should be identified, classified, and consequently regulated, as posing a carcinogenic risk to humans. It is OSHA's intention, once this proposal is duly promulgated, to foreclose, in the subsequent 6(b) rulemakings on individual substances, the rehearing of the validity of this classification system and most other policy determinations made in this proposal, including the procedural structure intended to be followed.

For example, one such foreclosed policy determination is whether employees shall be exposed to potential occupational carcinogens above the lowest level feasible. Accordingly, during the subsequent section 6(b) proceedings, interested parties would be foreclosed from the present endless debate concerning whether permissible exposure limits to humans can be related or extrapolated to those levels of exposure in test animals that indicated evidence of carcinogenesis.

OSHA intends and expects that these and the other issues raised by this proposal will be fully discussed, debated and aired in this rulemaking proceeding. At the conclusion of these proceedings, these policy decisions, including the regulatory framework embodied in this new Part 1990, will have been subjected to public proceedings, their scientific bases debated, and their consequences delineated. Based on the record fully developed in this proceeding, the scientific and related policy determinations will be made in the final regulations. Consequently, the Agency believes that this "generic" form of standard setting will not in any way shortcut "due process", the statutory procedural requirements set forth in section 6(b) of the Act or in 5 U.S.C. 553, *et seq.*, since every opportunity for notice, comment, and public participation in extensive hearings pursuant to those provisions will have been afforded.

It has long been recognized by the courts that regulatory agencies, such as OSHA, must and should use innovative rulemaking procedures to set policy, in order to comply with their statutory mandates, even at the expense of nominally depriving interested parties of a hearing on individual claims which may be contrary to the generally announced policy. Thus in 1956, the Supreme Court held that the Federal Communications Commission was not required to give a license applicant a statutorily required hearing, when the applicant did not qualify under the Commission's policy, adopted through rulemaking, that no person could own more than 5 broadcasting stations. (*United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 202 (1956). *See also, FPC* v. *Texaco*, 377 U.S. 33 (1964); *Airline Pilots Asso.* v. *Quesada*, 276 F. 2d 892 (2d Cir. 1960).

The overriding concern in these cases was whether parties had unreasonably been deprived of statutory procedural rights which were intended to assure that the agency would not act arbitrarily in denying claims. OSHA believes that no such deprivation will occur as the result of promulgation of these proposed regulations.

Rather, we believe that the combination of the broadly based rulemaking hearing and proceeding concerning this proposal and the subsequent section 6(b) proceedings on individual standards will provide all parties with ample opportunity to present their views and comments at the most relevant procedural stages. Certain policy determinations will be foreclosed from rehearing at the subsequent section 6(b) hearings. Those decisions based more on factual considerations, such as the applicability of the content of specific protective provisions as monitoring, respirator use and protective clothing, may be open in the section 6(b) proceeding depending on whether the unique properties of the substance are shown to warrant an exception to the general policy.

In addition, the following questions may also be at issue in the subsequent

proceedings relating to individual substances: (1) Whether the Secretary correctly classified the toxic material according to the appropriate criteria, (2) whether the Secretary correctly decided that the classification should not be rebutted, (3) the determination of the lowest feasible occupational exposure, or whether there are suitable substitutes found that are less hazardous to humans than the toxic materials, (4) the appropriateness and feasibility of the specific protective measures of the proposed standard and (5) the environmental impact arising from regulation of the toxic material.

Therefore, OSHA believes the flexibility and fairness of the individual substance-by-substance approach will be preserved by the procedures and policies incorporated in this proposal, for the feasibility and appropriateness of the protective provisions as applied to a given substance will be fully discussed at the rulemaking, concerning the specific substance, held pursuant to this Part and subpart. Yet OSHA's policy and factual judgments, based mainly "on the frontiers of scientific knowledge" with a "command to act", will be established after opportunity for full public participation in this rulemaking, and any future amendments thereto, and will not be allowed to be relitigated in "the standard-by-standard or substance-by-substance process".

II. Criteria for the Identification of Toxic Substances That Pose a Carcinogenic Risk to Man

For the reasons discussed below, there are currently two principal methods to identify the carcinogenic potential of any substance, namely, studies of human experience and tests on animals. In determing whether a toxic substance poses a carcinogenic risk to humans, OSHA intends, in general, to primarily rely upon evidence from these two methods, namely, human epidemiological studies, animal studies, or both. Two other possible methods to identify the carcinogenic potential of a substance—molecular structure (or similarity) and short-term tests—are also discussed, but OSHA will not, at this time, place sole reliance upon short term tests, and will not place any reliance on molecular structure or similarity for the reasons discussed below. OSHA invites public comment on all aspects of this specific part of this proposal.

While human studies are valuable, they cannot be the sole basis for regulatory decision making. Three overwhelming considerations generally require reliance upon laboratory animal testing insofar as carcinogenicity or other irreversible effects are concerned:

(1) As an ethical or moral matter, humans should never be used deliberately and prospectively as test subjects to determine the carcinogencity of a substance. This principle has been affirmed in *Ethyl Corp* v. *EPA*, *supra* at p. 26:

> Lastly, significant exposure * * * is toxic, so that considerations of decency and morality limit the flexibility of experiments on humans that would otherwise accelerate lead exposures from years to months, and measure these results.[55] *Cf. Environmental Defense Fund Inc.* v. *EPA* (shell), 167 U.S. App. D.C. 71, 78, 510 F. 2d 1292, 1299 (1975).

As FDA recently stated in issuing its final "Criteria and Procedures for Evaluating Assays for Carcinogenic Residues" in food producing animals (42 FR 10412, 10418; February 22, 1977):

> As a source of information, direct carcinogenesis testing of chemical compounds in man is and must remain beyond the ethical bounds placed by society on human experimentation. In the absence of this source of information, which incidentally would be the most relevant, alternate sources are human epidemiology studies and animal experimentation. Human epidemiology may provide post facto information about the carcinogenic effects of chemical compounds on man. However, while potentially useful in assessing the significance of new exposures or the risk posed by related compounds, such experience cannot be a central basis for * * * safety evaluations for several reasons, including the same ethical objections that make direct experimentation in man unacceptable.

(2) Moreover, even if such testing were condoned, an agency would have to wait for the linking of individual human cancers to exposure to the carcinogen pending the usual long latency period of 5 to 40 years before meaningful results could be obtained. This is, of course, not necessarily so in the case of lead, referred to by the Court of Appeals in *Ethyl Corp* v. *EPA*. As the Ad Hoc NIC Committee reported to the Surgeon General in 1970:

> Because the latent period in human carcinogenesis is so long, epidemiologic evidence develops only over periods of 15 to 20 years. Timely decisions to exclude materials from uses involving exposure to man, therefore, must be based solely on adequately conducted animal bioassays. Retrospective human evidence of risk must not be allowed to show itself before controlling action is taken. (p. 8)

(3) It is extremely difficult to construct a valid human study because humans are continually exposed to many toxic materials, most of which are not known either to be carcinogenic or not. See, *eq. EDF* v. *EPA*, 510 F. 2d 1292 (D.C. Cir. 1975).

A. Human Studies

Identification of carcinogens through human experience requires comparing cancer risk for selected groups of individuals exposed to known agents with the risk for a similar population that either has not been exposed to the same agents or has been exposed but at significantly lower levels. Such population, or epidemiological, studies have tended to focus upon occupational groups because of their relatively high or consistent exposures to substances often found in the workplace.

Several problems however exist in using human studies, although epidemiological studies can provide strong evidence of the causal relationship between exposure and disease, particularly when the findings are positive. Negative studies are difficult to interpret for the reasons discussed below. Although experiments on humans should never be used prospectively, as pointed out above, to wait for retrospective studies, based on *post hoc* investigation, clearly subjects workers to massive, involuntary human experiments with their attendant tragedies years later. Indeed:

> [e]xisting epidemiologic methods are adequate for demonstrating carcinogenic hazards in the work environment even when the excess risk is rather small and the disease in question is relatively common in the general population * * *. [But] * * * this capacity for recognition depends on the actual occurrence of disease and, by itself, has no preventive or control value. (Cole and Goldman, in Fraumeni, Persons at High Risk of Cancer, Natl. Cancer Inst., 1975, p. 177.)

Also acknowledged is that:

> * * * all public health approaches to the prevention of occupational cancer are to complement, not replace or make less stringent, the industrial hygiene practices that should be in effect. (*Ibid.*, p. 179.)

In addition, often severe reliability problems exist which limit the value of human studies. As Fraumeni pointed out:

> [i]t seems likely that existing epidemiologic methods will allow the identification of groups at high risk of cancer because of their occupational experience * * * [t]hese methods are imperfect, however, and limitations in study design and types of data should be borne in mind when occupational carcinogensis is studied. (*Ibid.*, p. 168.)

First, an important characteristic of carcinogenesis is the apparent variability in individual susceptibility. Since carcinogenesis results from the interaction of the toxic material with the biological target, the effect is qualified by the susceptibility of various cell types, various tissues or organs and various individuals as has been pointed out above. It has been found that individual variability in response to carcinogens is great. Factors such as age, sex, hormonal status, diet and nutritional conditions, genetic factors, individual variations in the metabolic handling of chemicals, or the combined effect of different chemicals, all contribute to determine the response of an individual to a chemical carcinogen; differneces in response in test animals as high as 100 fold or 1000 fold can be obtained by changing only one factor at a time. Thus, valid epidemiological studies are difficult to conduct because study population groups tend to be small and reactions to a single carcinogen may not appear in the study groups due to the varying degrees of susceptibility.

Second, these difficulties are further complicated by the latency period between exposure and cancer symptoms. It usually takes 5–40 years between exposure to a cancer-producing chemical and manifestation of the disease.

Generally, the greater the exposure, the shorter the latency period. In one study of bladder tumors among 78 aromatic amine workers, for instance, the length of exposure appears to correlate

[55] It is for these reasons that, although lead additives have been used for over 50 years, the danger posed by lead emissions is still a question "on the frontiers of scientific knowledge.' *Industrial Union Department, AFL-CIO* v. *Hodgson, supra* ** *".

inversely with the length of the latency period—the greater the exposure, the shorter the latency. Because so many factors influence latency, however, it is impossible to define the extent to which the length and degree of exposure may be important.

Latency poses troublesome medical, social, and economic implications for identifying hazardous contaminants in the environment. Chemicals may appear safe for human exposure after they have been used for 10 to 15 years without obvious harm. With carcinogens, however, the lack of demonstrated damage to health even after this comparatively long period presents a false sense of security. Thirty or 40 years may be required before enough individuals have been exposed to a carcinogen to produce detectable cancers. The long delay between exposure and symptoms and the irreversibility of the disease often makes it medically and scientifically impossible to identify carcinogens in the environment.

Detection difficulties posed by the latency period are compounded by the mobility of our society. People in this country change jobs, residences, and, consequently, doctors and hospitals relatively frequently, so that even large-scale adverse health effects from latent diseases may be undetected. Moreover, people are exposed to carcinogens in great variety and concentration not only on the job but in their diets and surrounding environments; this multiplicity of exposure further complicates identification of the causes for any given cancer.

And third, epidemiological studies are difficult to conduct because seldom is it possible to isolate a single variable for study because of the complex mix of chemical agents to which humans are exposed in their work and other environments. In the real world, obviously, workers are exposed to a combination of substances, rather than just one chemical. Often exposure levels are difficult to define. Individual resistance to participation in tests and an investigator's inability to obtain medical histories and records may also hamper a study. Some chemicals are virtually everywhere in the environment, but at low concentrations—a combination of circumstances which presents formidable problems of safety assessment for investigators. It will be extremely difficult, for example, to assess the carcinogenic impact of the pesticide dieldrin because residues are found in 99 percent of the U.S. population. More important, perhaps, is the possible synergistic effects of that substance in workers who are exposed to other cancer causing agents. The Ad Hoc NCI Committee recognized this posibility in 1970 when it stated:

> It has become increasingly obvious that the hazard from a single chemical carcinogen cannot be evaluated out of a context of the total environmental exposure. Estimation of the "cumulative carcinogenic dose" resulting from all possible chemical carcinogens or even from all sources of a single type or class of chemical carcinogens is presently impossible. (P. 3)

The same state of science exist today although the theory is perhaps confirmed. As the Administrator of EPA stated in 1975, in denying the use of the pesticide DDT in Louisiana:

> In addition, evidence reviewed by me in September 1974 that had been introduced in the Aldrin/Dieldrin suspension hearing revealed the apparent synergistic effects on the development of tumors in mice fed DDT and Dieldrin in combination. (39 FR at 37268) While such a possibility had long been feared, this was the first evidence actually demonstrating such effects. (40 FR 15940, April 8, 1975)

Thus, even if the effects of a carcinogen can be unequivocally demonstrated as soon as those first exposed manifest symptoms of cancer (rarely the case because their first exposure occurred 5–40 years earlier) and even if exposure can be immediately eliminated and we could solve the problem of synergism, mankind still faces several decades of cancer in individuals who have already been exposed but who have not yet manifested symptoms. In those circumstances, there is nothing any regulatory agency can do to prevent the disease. Thus, what is true of carcinogenesis for an individual or a working population is also true for society, namely that an epidemic of cancer may be in the making while exposure to the unknown carcinogenic agent continues for decades, multiplying its potential effects.

B. ANIMAL STUDIES

Because we have been unable to identify with sufficient precision the causes of cancer in humans already affected and because it is unacceptable to wait for additional cases of human cancer to provide the scientific evidence needed, investigators have long relied upon laboratory tests with animals to study the carcinogenic potential of chemicals. We discuss the general propositions herein, although we recognize that some of the opinions of the distinguished bodies discussed go father than, or not quite as far as, some of the positions taken in these proposed regulations.

For all practical purposes, the detection of carcinogenic activity of chemicals is based on animal experimentation. All chemical substances or mixtures that have been proven carcinogenic by direct observation in man have also been shown to be carcinogenic in experimental animals (with the possible exception of arsenic and benzene, still under experimental study). Because of the difficulties of epidemiological studies on humans exposed to potential carcinogens stated above, there are usually no data which provide us with any evidence—one way or another—whether cancer is caused in man by a chemical that has been shown to be carcinogenic in animal studies. However, not to at least qualitatively assume that such a chemical does pose a carcinogenic threat to man seems imprudent and could lead to disaster. As the Ad Hoc NCI Committee's report to the Surgeon General stated in 1970:

> Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man. (P. 1)

Indeed, OSHA has long ago accepted this principle. In the preamble to the standards for the 14 carcinogens, OSHA stated:

> A major question of occupational carcinogenesis relates to the extrapolation of results of animal experimentation to humans. The basis of numerous objections to the proposals is that, even assuming the validity of animal experiments, such do not furnish sufficient evidence that the substances involved are carcinogenic to humans. Extrapolation of results obtained by animal experimentation is alleged to be vitiated by several considerations: (a) That certain cancers are specific only to some species; (b) that the conditions of animal experiments are out of proportion to, and not consistent with conditions prevailing in industrial exposure; and (c) that no cancers have yet been detected in humans exposed to the substances. For those substances whose metabolism is understood, and is similar in both animals and man, the fact that they induce cancers in animals warrants the expectation that they will induce cancers in men. This applies to the substances which cause urinary bladder cancers in animals acting, not directly, but indirectly through the mediation of metabolites formed both in experimental animals and in exposed workers. This is also true of those substances which apparently require no metabolic alteration but attack a particular biologic system (e.g., respiratory tract, alimentary canal) which is similar in both animals and humans.
>
> The objections raise the much broader issue of human exposure to a chemical which is only known to have caused cancers in experimental animals. It is important to note that some opponents of the regulation of such chemicals do not advocate treating them as if they were harmless with respect to carcinogenic potential. Several employers, for instance insist that such substances must be treated with "care" or "respect," while also insisting that they call for significantly less protection than those substances known to be human carcinogens.
>
> We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either noncarcinogenic or carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic to man.
>
> We agree with the Director of NIOSH, and the report of the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, U.S. Public Health Service, April 22, 1970, that the second alternative is the responsible and correct one. This decision accords with the work practices of some who object to the proposed regulation. (39 FR 3756 at 3757–58)

Moreover, in regulating ethyleneimine (EI) in 1974 as a carcinogen, OSHA stated:

> The carcinogenic potential of ethyleneimine (EI) has been confirmed by a study conducted by Walpole in 1954 involving rats and one sponsored by the National Cancer Institute involving mice. In the first study, animals developed injection site sarcomas

which the investigators attributed to the direct action of Ethyleneimine, and in the second study 80 percent of the animals developed tumors, including more than one-half with hepatomas (which the investigators stated had "malginant potentiality") and almost three-quarters with pulmonary tumors. Although high doses of EI were administered, the investigators stated there was no way to predict whether man would be more or less susceptible to tumor induction by EI.

The case for the carcinogenicity of EI, then, rests on the extrapolation to humans of the findings in two separate, controlled animal studies. The position is compatible with that of NIOSH concerning the prior demonstration of carcinogenicity in at least two animal studies. (39 FR 3756 at 3757)

This position was affirmed by the Third Circuit which held in *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F. 2d 1155, 1160 (3d Cir. 1974) that: "There does exist substantial evidence in the record as a whole to support the Secretary's finding that EI is carcinogenic in rats and mice and, in the absence of evidence of carcinogenicity in humans, the Secretary properly weighed the only available alternatives."

In *In Re Shell supra*, The EPA Administrator agreed:

The ultimate issue in this suspension proceeding is whether Aldrin-Dieldrin is carcinogenic in man. Because man's response to carcinogens is similar to that of rodents, the finding that a substance is carcinogenic in experimental animals indicates that it poses a similar risk to man.

In affirming that decision, the Court of Appeals for the District of Columbia stated at 510 F. 2d at 1299:

The validity of extrapolation to humans from data derived from tests on animals is also a matter within the agency's expertise. There was testimony before the Administrator to support such extrapolation and this court has acknowledged the significance of test animal data when cancer is involved. Use of animal data is particularly appropriate where, as here, accurate epidemiological studies cannot be conducted because the virtually universal contamination of humans by residues of aldrin/dieldrin make it impossible to establish an uncontaminated human control group. The long latency period of carcinogens further hinders epidemiological research, and the ethical problems of conducting cancer experiments on human beings are too obvious to require discussion. Although extrapolation of data from mice to men may be quantitatively imprecise, it is sufficient to establish a "substantial likelihood" that harm will result. *Cf. Society of Plastics Industry, Inc.* v. *OSHA*, 509 F. 2d 1301, at 1308 (2d Cir. 1975).

And in proposing to ban the use of chloroform in drug and cosmetic products, FDA stated (41 FR 15027):

Although he is not aware of any direct evidence that chloroform induces cancer in man, the Commissioner recognizes that the positive finding of cancer in test animals in the National Cancer Institute report indicates cholorform may pose a risk of cancer for humans. Experience has indicated that, with one or two possible exceptions, compounds that are carcinogenic in humans are also carcinogenic in one or more experimental animal bioassay systems. In addition, several compounds first detected as a carcinogen in experimental animals were later found to cause human cancer. The clear demonstration that a compound is carcinogenic in experimental animals must, therefore, be taken as evidence that it has a potential for carcinogenesis in humans unless there is strong evidence to the contrary.

In finalizing that decision some two months later, FDA stated (41 FR 26844):

The Commissioner considers the fact that a substance has been shown to be an animal carcinogen must be taken as evidence that it has a potential for carcinogenisis in humans unless there is strong evidence to the contrary.

And, in banning "TRIS", the Consumer Product Safety Commission stated:

The Commission has no conclusive data that establish that TRIS has caused cancer in humans. Since cancers develop over many years and cannot be easily linked to particular causes, this is not unexpected. The Commission's Office of the Medical Director (OMD) believes that once a substance is established as an animal carcinogen it can never be assured as a safe substance for human exposure. In addition, OMD believes that all known human carcinogens have been shown to be carcinogenic in laboratory animals. (Footnotes omitted). (42 FR 28060 at 28061, June 1, 1977)

Animal studies are most often conducted on small mammalian rodents such as mice, hamsters, and rats. Although as mammals, rodents are biologically closer to humans than fish, birds, or invertebrates, the choice of rodents as test species is not based solely upon their similarity to man. In large part, they are chosen for scientific convenience; they are small, easy to breed, relatively inexpensive to maintain, and have gestation periods of only a few weeks, so that an investigator can study many generations of rodents in a single year. Most important, cancers with a latency period of 5–40 years in humans will show up in rodents in only 1 to 2 years.

Animal studies typically use either a heterogeneous group of animals—one exhibiting a wide variety of physical and physiological traits, as humans do—or a carefully inbred strain that continues to exhibit the same well-defined characteristics generation after generation. Inbred strains offer experimental advantages and disadvantages; in studies of the carcinogenic potential of ultraviolet radiation on the skin, for example, hairless strains eliminate the need for removing the test animal's hair so that radiation can reach the skin. On the other hand, an inbred strain may have either an atypical sensitivity or resistance to the carcinogenic effects of a chemical. Repeated results can often be obtained with smaller numbers when animals of an inbred strain are used because of less variation due to genetic variation.

The chemical being tested may be administered to the animal in any one of several ways, for example: By ingestion through food or water, inhalation, injection under the skin or through the skin into the peritoneum, application to the skin, or directly to the stomach by means of a throat tube (gavage). Ingestion, inhalation, and skin application correlate with the normal modes of human exposure. Injection and a tube to the stomach are the favored methods when the amount of exposure must be measured precisely.

The validity of extrapolating animal test results to man is firmly based upon empirical evidence as we point out below. Not only have mammalian experiments given positive carcinogenic test results for every compound known to cause cancer in man, except arsenic and perhaps benzene; although there may be wide variations in the susceptibility of various species to cancer, evidence indicates that a chemical that causes cancer in one animal species is likely to do so in most other species tested. The preponderance of scientific data indicates, in sum, that laboratory animals are suitable test models for determining the cancer causing potential of a toxic substance to humans.

In "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances", recently proposed for NCI by the Subcommittee on Environmental Carcinogenesis of its National Cancer Advisory Board (NCAB Report), 58 JNCI 461 (Feb. 1977) the expert subcommittee stated that studies with animal populations represent "a major source of data on carcinogenicity". Although present knowledge is not sufficiently advanced to allow a precise determination of whether a carinogen identified solely by means of a bioassay in animals will or will not be carcinogenic in man and because it is not ethically nor practically feasible to undertake to study the effects on man of substances identified as carcinogens through animal studies, it is necessary to rely on the correlation between substances studied in animals and those known to induce cancer in man. The NCAB Report states that:

[e]xperience has indicated that, with one or two possible exceptions, compounds that are carcinogenic in humans are also carcinogenic in one or more experimental animal bioassay systems. In addition, several compounds first detected as carcinogens in experimental animals were later found to cause human cancer. Demonstration that a compound is carcinogenic in animals should therefore, be considered evidence that is likely to be carcinogenic in humans, unless there is strong evidence in humans to the contrary.

The validity of using animal data as a qualitative indication of potential human effects has long been recognized by scientific advisory committees, and other governmental bodies; portions of the extensive discussion by expert committees, of the general criteria and principles applied to the design and interpretation of studies in animals will be traced to illustrate the varying conditions accepted for testing for carcinogenicity in animals (including length of the exposure period, number of animals to be employed, kinds of controls to be used, etc.) and the necessity for reliance on such data despite considerable uncertainties. As far back as 1959, a report of the National Research Council's Food Protection Committee provided one of the earliest reviews of the problems of identifying carcinogens. In the case of food additives, it was noted that epidemiological studies were even more difficult to conduct than for occu-

pational exposures, and a series of general considerations and principles underlying evaluations of carinogenicity from animal studies were outlined. The report stated with regard to substances studied by administration to experimental animals that:

[t]here is general agreement as to the carcinogenicity of these substances and, although the carcinogenicity of all of them for man has not been demonstrated, it is unlikely that anyone would defend the addition of any of them to the human diet. (NRC, 1959, p. 6)

In 1961, a joint committee of the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) issued a report entitled: "Evaluation of the Carcinogenic Hazards of Food Additives" (WHO Tech. Rept. 220). The committee, in its report, noted the "* * * difficulty of carrying out and interpreting epidemiological studies" and recognized that tests in animals are necessary to identify carcinogens. The committee stated that:

* * * tests on experimental animals cannot provide irrefutable proof of the safety or carcinogenicity of a substance for the human species. However, it is at least reassuring that the known carcinogenic activities of certain chemicals in man are similar in many ways to those found in experimental animals. (WHO Tech. Rept. 220. p. 6)

As a minimum safeguard, the committee said an "* * * investigation of the tumor incidence in a chronic toxicity test * * *" should be performed, which "* * * should involve the study of an adequate number of animals of two species (*e.g.*, rats and mice) and subjected to the feeding of a suitable dose range of the substance under question for the lifetime of the animals." (*Ibid.*, p. 7)

The committee also noted its view of the need to use sensitive animals and stated:

Both sexes of each of at least two species of animals should be used in the tests throughout their lifespan. In most cases these species would be rats and mice. Hamsters or dogs might be suitable, but guinea-pigs, for example, appear to be resistant to some known carcinogens. The use of dogs in carcinogenicity tests has disadvantages. Because of the expense of maintenance, it is difficult to use a sufficient number to detect a low incidence of cancer, and the life span of the animal is 12–15 years. (*Ibid.*, p. 8)

The committee report further stated that to establish valid negative results requires either the "unrealistic" use of large numbers of animals or dose levels "* * * far in excess of those recommended for human consumption." (*Ibid.*, p. 9) Thus, to reduce the possibility that studies in animals will be too insensitive to detect the carcinogenic action of a substance, large doses of the substance are administered to the animals, despite the fact that in some cases large doses of many substances may cause nonlethal, non-carcinogenic but toxic effects in animals.

A report published in 1969 by the International Union Against Cancer (UIAC, 1969) discussed the results of a study of "* * * those aspects of experimental carcinogenesis in animals which have a direct bearing on the problems of environmental cancer in man * * *" with particular emphasis on "* * * methods of testing substances suspected of being carcinogenic in man, and to problems related to testing procedures." (UIAC, 1969, p. 1). The report states:

The need to formulate minimal requirements for satisfactory testing of substances suspected of being carcinogenic for man, has been recognized for a long time, and a number of international and regional bodies had already discussed it in some detail and published specific recommendations * * *. These earlier recommendations differed one from another in several respects, due in part to conflicting views among the various experts in the field, though some of the divergencies of opinion were more concerned with differences between minimal and optimal requirements. (*Ibid.*, p. 11)

The report then discussed the minimal, and to some extent desirable, procedures to be employed in animal bioassays for carcinogenicity, the presentation of data, their interpretation, and other points, including priorities for testing. In the report it was also stated that positive findings should outweigh negative results:

It is generally recognized that negative results of biological testing are less significant than positive results, in relation to human application. This is all the more true when testing procedures are inadequate. (*Ibid.*, p. 18)

In the United States, a review of concepts to be applied in carcinogenicity testing was also published in 1969 by the Commission on Pesticides and Their Relationship to Environmental Health, appointed by the Secretary of the Department of Health, Education, and Welfare (Mrak Commission). The Technical Panel on Carcinogenicity recommended that food additives and contaminants be tested for possible carcinogenic effects by means of adequate long-term bioassays.

The minimum requirements for such bioassays should include: Adequate numbers of animals of at least two species and both sexes with adequate positive and negative controls, subjected for their lifetime to the feeding of a suitable dose range of the test material, including doses considerably higher than would be present in food * * * any substance which is shown conclusively to cause cancers in animals when tested under these conditions should be considered potentially carcinogenic for man * * *. (Mark Commission, p. 467)

* * * * *

* * * the number of animals in each test group should be sufficient throughout the tests to yield statistically significant results. It is important to stress that the detection of positive results in these bioassays depends on the development of tumor incidences significantly above the threshold of detectability for a given number of animals. Any carcinogenic effect below these levels will not be detected by the bioassays used. (*Ibid.*, p. 465)

* * * * *

The species most practical for testing are rats, mice, and—as more recently shown—hamsters. Strains and colonies should be selected to provide adequate sensitivity to tumor induction, as revealed by positive control tests with known carcinogens. (*Ibid.*, p. 465)

The Technical Panel noted (footnote 2 on p. 465) that:

[t]he use of nonrodent species, recommended in the earlier reports, has now been substantially dropped. A suitable, practical nonrodent species would be useful but it is not available at this time * * *. While dogs have been employed for tests of carcinogenicity, with noteworthy success in selected cases (bladder carcinogenicity of aromatic amines), the requirement of lifetime feeding makes this species too expensive, in terms of time and funds, to be employed routinely.

The Technical Panel also noted the:

[g]eneral principles and criteria for evaluation of carcinogenic hazards * * * laid down by several expert committees conceived in the last fifteen years by scientific and public health agencies * * *.

and stated that:

Recommendations made in these reports express a remarkably unanimous view on the general principles and criteria to be followed for carcinogenesis safety evaluations, widely accepted in principle by the scientific community (references omitted). (*Ibid.*, p. 464)

In the report, the Technical Panel discussed the uncertainties as to the relevance and extrapolation of animal data to man, which it was stated:

* * * are a cause for concern and caution in interpretation of results. It should be noted, however, that a remarkable degree of concurrence has been found to exist between chemical carcinogenesis in animals and that in man where it has been studied closely. (*Ibid.*, p. 482)

Thus, in recommending that human exposure to those pesticides considered to present a potential health hazard to man should be reduced, the Mrak Commission cautioned that:

* * * it is of utmost importance that the results of screening tests be scientifically and rationally considered. The correct interpretation of hazards to human health is sometimes extraordinarily difficult. It must involve the transfer of the results of animal experiments to prediction of human effects. In addition, the screening process frequently involves preliminary examination of the effects of massive dosages, possible contamination of test samples, and other factors which affect proper interpretation * * * [but] * * * [t]he health and welfare of the public must be effectively protected. (*Ibid.*, p. 10)

Also in 1969, a Panel on Carcinogenesis of FDA's Advisory Committee on Protocols for Safety Evaluation prepared a report (FDA Panel Report) and later published it ("Panel on Carcinogenesis Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides," *Toxic and Appl. Pharmacol., 20,* 419 (1971)). The FDA Panel concerned itself "* * * with an evaluation of the present status of testing for carcinogenic action of food additives and other chemicals, which come into contact with man principally through his diet * * * and * * * consideration of recommended test procedures for carcinogen-

sis (p. 425). A number of issues involved in the reliance on tests in animals under controlled conditions were discussed. Of the species of animals that might be used, the Panel said:

There is general recognition that new species in addition to the commonly used rodents are needed for carcinogenicity testing. Increasing the number of species used would greatly increase the margin of confidence with which safety can be predicted * * *. The most discussed additional species are primates. Recent studies show certain primates to be highly susceptible to some carcinogens; however, much more work is needed to justify the additional expense and time that would be necessitated by the introduction of these animals in routine test procedures. (FDA Panel Report, p. 426)

And in a discussion of the use of dogs, the Panel said:

There is general agreement that the dog is not a practical test animal because of its size and relatively long life span. (*Ibid.*, p. 426)

The FDA Panel also delineated the responses in experimental animals as compared with a series of untreated (control) animals that "* * * may suggest the presence of a carcinogenic hazard * * *." They are:

* * * (1) an increased incidence of tumors of a type seen commonly in the control animals, (2) an occurrence of a type of tumor not seen at all in the control animals or (3) a combination of the occurrence of a different type of tumor and an increased incidence of one or several types of tumors seen in the controls. In some experiments the only manifestation of an effect consists of (4) an earlier occurence of tumors in the treated animals than in the controls, the incidence being the same in both. In yet another variation the only effect seen may consist of (5) an increase in the number of tumors per animal, the number of tumor bearing animals being the same. (*Ibid.*, 419–420)

In 1969, the NRC Food Protection Committee prepared another report, "Evaluating the Safety of Food Chemicals," which was published in 1970 (NRC, 1970). The Committee noted that the previous reports of the Food Protection Committee, the Joint FAO/WHO Expert Committee, and the FDA contained:

* * * complementary statements of the principles underlying evaluation of the safety of food chemicals and * * * set forth proposed procedures for accomplishing the evaluation * * *. (NRC), 1970, p. 1)

The Committee stated that it was:

* * * not the purpose of this report to present another set of principles and procedures, but rather to review the purposes and value of what have become conventional procedures * * *. (*Ibid.*, p. 1)

The Committee discussed the difficulty in carrying out controlled epidemiological studies and stated that:

[c]ontrolled experimental studies in man, though desirable, have limited predictive value * * *. (*Ibid.*, p. 44)

and therefore:

[i]t is clear that appropriate and well-executed animal studies are more likely to provide a substantial background of biological data from which to judge safety than are studies in man alone. (*Ibid.*, p. 45)

In a discussion of the evaluation of the carcinogenic hazards of chemicals for man, the Committee stated that:

[o]n both ethical and practical grounds, the possible carcinogenic effects of chemicals to which man might be exposed must be determined in experimental animals, generally in short-lived species. The extrapolation of the results of these determinations to man rests on two basic findings:

1. Despite a great variety of studies, no significant aspect of the natural occurrence, induction, and properties of cancer has been shown to differ fundamentally between man and experimental animals.

2. Considerable assurance of the general applicability of the tests can be derived from the fact that the chemicals generally known to be carcinogenic in man also induce neoplasia (tumors) in experimental animals.

Many clear differences in the activities of chemical carcinogens in various species exist, however, and the unpredictable nature of species differences is the principal limitation to the extrapolation of results from studies with experimental animals to man. (*Ibid.*, p. 47)

In 1970, the report, prepared for the Surgeon General by the Ad Hoc Committee of NIC, dealt with problems of exposure to chemical agents from all sources and "* * * the scientific criteria for evaluation of carcinogenic hazards." (NCI, 1970, p. 1). In emphasizing the broader scope of their report, the Committee said:

[M]any previous recommendations on the criteria to be used for evaluating environmental chemical carcinogenic hazards have been made for specific sources of exposure or for specific groups of substances (e.g. food additives, pesticides, certain occupational carcinogens). In some cases this approach has led to an uneven assessment of risks from different sources and to an uneven approach to preventive measures. (*Ibid.*, p. 1)

The Committee acknowledged that:

[t]he present state of the art requires long-term bioassays in mammalian species for the experimental identification of carcinogenic activity * * *. A body of knowledge has developed over the years on the response of experimental animals to chemical carcinogens. Several committees of experts in the field of carcinogenesis convened by national and international bodies over the past 15 years have formulated general principles for performance and evaluation of carcinogenesis studies in animals. The recommendations put forth by these committees have shown remarkable unanimity (specifically cited were WHO Tech Repts 276 and 220, FDA Panel Report, Mrak Commission Report) and are widely accepted in principle by the scientific community[6] (*Ibid.*, p. 1)

Among the Committee's recommendations were:

Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man. Exceptions should be considered only where the carcinogenic effect is clearly shown to result from physical, rather than chemical, induction, or where the route of administration is shown to be grossly inappropriate in terms of conceivable human exposure.

Data on carcinogenic effects in man are only acceptable when they represent critically evaluated results of adequately conducted epidemiological studies.

* * * Evidence of negative results, under the conditions of the test used, should be considered superseded by positive findings in other tests. Evidence of positive results should remain definitive, unless and until new evidence conclusively proves that the prior results were not causally related to the exposure.

* * * A basic distinction should be made between intentional and unintentional exposures.

* * * No substance developed primarily for uses involving exposure to man should be allowed for wide-spread human intake without having been properly tested for carcinogenicity and found negative.

* * * Any substance developed for use not primarily involving exposure in man but nevertheless resulting in such exposure, if found to be carcinogenic, should be either prevented from entering the environment or, if it already exists in the environment, progressively eliminated. (*Ibid.*, pp. 1, 2)

The Committee also stated:

Any substance which is [validly] shown conclusively to produce tumors in animals * * * should be considered potentially carcinogenic for man. (*Ibid.*, p. 7)

More recent reports further confirm the widely recognized validity of animal experiments for establishing the carcinogenic potential of substances. An ongoing series of monographs published by the International Agency for Research on Cancer of WHO (IARC) beginning in 1972 lists animal data and any epidemiological evidence of cancer in man when discussing the carcinogenic potential of individual substances or of classes of substances. The monographs were initiated as a result of a recommendation in 1970 of the IARC Advisory Committee on Environmental Carcinogenesis:

* * * that a compendium on carcinogenic chemicals be prepared by experts. The biological activity and evaluation of practical importance to public health should be referenced and documented. (IARC Monographs, Vol. 1, p. 8)

The stated objective of the monographs is:

* * * to achieve a balanced evaluation of data through the deliberations of an international group of experts in chemical carcinogenesis and to put into perspective the present state of knowledge with the final aim of evaluating the data in terms of possible human risk, as well as to indicate the need of research efforts. (IARC Monographs, Vol. 1, p. 8)

---

[6] The committee cited the following references: P. Shubik and J. Sice, "Chemical carcinogenesis as a chronic toxicity test: A Review," *Cancer Res. 61*, 728 (1956). D. B. Clayson, "Chemical Carcinogenesis," Boston, Massachusetts, Little Brown and Co., 1962. W. C. Hueper, W. D. Conway, "Chemical Carcinogenesis and Cancers," Springfield, Illinois, C. C. Thomas, 1964. J. H. Weisburger and E. K. Weisburger, "Tests for Chemical Carcinogens, *In* Methods in Cancer Research, Volume I. (H. Busch, ed.), New York, New York, Academic Press Inc., 1967, pp. 307–387. J. G. Arcos, M. G. Argus, G. Wolf, "Testing Procedures," In "Chemical Induction of Cancer," Volume I (J. G. Arcos, M. G. Argus, and G. Wolf, eds.), New York, New York, Academic Press Inc., 6968, pp. 340–463.

The monographs emphasized that the response to a carcinogen in animals may be observed in several forms:

(a) as a significant increase in the frequency of one or several types of neoplasm, as compared with other than zero frequency in control animals;

(b) as the occurrence of neoplasms not observed in control animals;

(c) as a decreased latent period as compared with control animals;

(d) as a combination of (a) and (c). (IARC Monographs, Vol. 1, p. 10)

In 1975, the National Research Council published two reports that addressed the question of carcinogenicity testing in animals. In a report on present and alternative technologies for pest control (NRC Pest Control), it is concluded:

• • • the carcinogenic risks, and other health hazards, of pesticides require continuing evaluation by testing with laboratory mammals; and that despite the problems involved in translating the results from such experiments to human risk, the present techniques are sufficiently reliable to justify registration actions based upon such data alone, on an interim basis, until evidence convincingly demonstrates that there is no human risk. (NRC Pest Control, Vol. 1, p. 5)

In a report on principles for evaluating chemicals in the environment (NRC Principles for Evaluating Chemicals), a section is devoted to chemical carcinogenesis which discussed aspects of experimental design for carcinogenicity testing. The report states:

[r]odents are the animals of choice for carcinogenesis tests because of their convenience, comparatively short life span and proven susceptibility to a broad range of carcinogenic agents. (NRC Principles for Evaluating Chemicals, p. 150)

In 1976 the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board, National Cancer Institute, issued a report entitled "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances" (NCAB Report), June 2, 1976. The report stated:

• • • Demonstration that a compound is carcinogenic in animals should, therefore, be considered evidence that it is likely to be carcinogenic in humans, unless there is strong evidence in humans to the contrary. (NCAB Report, p. 2)

The report also stated:

Because of the limitations inherent in animal bioassays, a negative result obtained in a particular animal bioassay does not exclude the potential carcinogenicity of a compound in humans. The inappropriate experimental species may have been chosen; the number of animals tested may have been too small; or the duration of observation may have been too short. Alternatively, test conditions may have been inappropriate in terms of their predictive value for the response of humans. The extrapolation of experimental carcinogenicity data to the human situation is strengthened by obtaining results in more than one species. Negative results obtained in one species do not, however, detract from the significance of clearly positive results obtained in another species. (NCAB Report, p. 9)

It would seem, therefore, that opinions of scientific experts generally are substantially in agreement on (1) the practical and ethical difficulties in relying on epidemiological studies in man as the basis for establishing the lack of a carcinogenic potental of substances; (2) the validity of studies in experimental animals to establish the carcinogenic potential of a substance; (3) the minimal and optimal experimental conditions for testing for carcinogenicity; and (4) the kinds of statistically significant changes in tumor incidents that may be observed in experimental animals and used to characterize carcinogenic potential.

In particular, there appears to be general agreement on some of the following major issues and OSHA relies upon these concepts in proposing these regulations:

1. *Mammalian Species.* Mammalian species are those species of test animals generally considered directly relevant to mon insofar as carcinogenicity testing is concerned. Other species, such as reptiles have not been shown to have any such similarity to humans, insofar as carcinogenity is concerned. Thus, OSHA relies, in general, only upon results found in testing of mammalism species. In that regard, the rat and mouse (and to a lesser extent the hamster) have traditionally been the species of choice for carcinogenicity testing, other mammalian species being useful for certain purposes but being generally impractical for use in full-scale bioassays (WHO Tech. Rept. 220, p. 8; Mrak Commission, p. 465; FDA Panel Report, p. 426; NRC Principles for Evaluating Chemicals, p. 150). The choice of the rat and mouse is not only dictated by considerations of convenience, but because of their known susceptibility to agents known to be carcinogenic in humans as well as the similarity in the mechanisms of tumor induction (NRC, 1970, p. 47).

In *In Re Shell, supra,* the EPA Administrator stated:

Most of what we know about cancer is derived from tests with experimental animals, usually mice. The response of mice to carcinogens is similar pathologically to that of man; and research laboratories, such as those of the National Cancer Institute and Shell Chemical Company, use mice extensively in their research. (Footnotes omitted)

In affirming the EPA action, the United States Court of Appeals for the District of Columbia stated, 510 F. 2d 1292 at 1299:

Shell claims that tests based on mouse data are not substantial evidence, because mouse livers are unusually susceptible to cancer. Still, Shell's data—of statistically significant incidence of malignant liver tumors—were in strains of mice that were, as was noted by the Administrator, unusually resistant to such tumors. In any event, Shell's objections are outweighed by the substantial evidence supporting EPA's determination that mice are not uniquely susceptible to carcinogens, but are, in fact, good predictors of carcinogenic hazard to man. The Administrator found that rodents are particularly useful experimental animals, in part because of the similarity of their response to carcinogens to the response of man, their short lifespan, and our relatively well-developed understanding of the pathological development of tumors in mice and rates. Respected research institutions such as the National Cancer Institute have used mice extensively because they have found mice to be an accurate predictor of cancer in other species. (omitting footnotes).

And, in *In Re Velsicol,* the EPA Administrator stated:

For these reasons, pesticides and other chemicals are tested for carcinogenicity in laboratory animals, particularly mice (the first choice) and rats, which are broadly accepted by the scientific community as appropriate test animals for these purposes.

The mouse develops almost every kind of cancer that occurs in man and, with few, if any, exceptions, is subject to cancer from any source which is known to be a carcinogen in man. In both mouse and man, genes are involved in the control of processes through which cancer is induced. They control reactions to physical and chemical carcinogens. The genetic characteristics of mouse and man are sufficiently similar to permit the assumption that if a chemical or other agent such as radiation causes cancer in a particular organ of mice, then it will also cause cancer in the same organ, or possibly some other organ, of man.

In fact, the difficulty with using laboratory animals to test for carcinogencity lies in the other direction. The failure of a chemical to induce cancers in a particular strain (or even several strains) of laboratory animals is not an assurance that the chemical is not a carcinogen in man, since that particular strain may be genetically resistant to cancer from that source, where, by contrast, the genetic susceptibility of people to cancer varies a great deal from person to person.

In the final determination to prohibit the use of chloroform in drug and cosmetic products, FDA was also faced with a study based on mice and rats. In discussing the issues raised concerning the mouse, FDA stated:

1. One comment from the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), which also submitted safety data to FDA on studies involving the use of chloroform, questions the relevancy, design, execution, and interpretation of the National Cancer Institute (NCI) studies, and expressed the opinion that it is scientifically unjustified to disregard CTFA's studies in favor of the NCI studies. The specific points raised by the comment in opposing the Commissioner's determination that chloroform is a carcinogen or is otherwise a deleterious substance are as follows:

a. The comment contends that the NCI studies in no way consider the differences in metabolism between rodents and man. In support of this contention regarding differences in metabolism, the comment cites an article by Hill et al., "Genetic Control of Chloroform Toxicity in Mice," *Science,* 190.159, 1975; a recent review by Charlesworth in BIBRA (British Industrial Biological Research Association) *Information Bulletin,* 14:225, 1975, which cites Taylor et al. in Xenobiotica, 4:165, 1974; and a paper entitled "Covalent Binding of Haloalkanes to Liver Constituents, but Absence of Mutagenicity on Bacteria in Metabolizing Test System" by Uehleke, Greim, Kramer and Werner, presented at the fifth meeting of the European Environmental Mutagen Society, Florence, October 19–22, 1975. The comment states that (1) Hill et al. demonstrated that there are genetic factors in mice that affect susceptibility to chlorofrom lethality and induction of organ pathology and that these are associated with a metabolite whose formation is regulated by genetic factors; (2) Charlesworth reported distinct species differences to show that the metabolic fate of chloroform in mice and most likely in rats,

is not the same as in man, that there are sex-linked differences in metabolism that are peculiar to the mouse, and that man appears to eliminate more of the chloroform unchanged in the exhaled air; (3) Taylor et al. concluded that the mouse is an unsuitable species for evaluating the toxic effects of chloroform; and (4) Uehleke found in the "Ames study" that chloroform is not mutagenic and unlikely to be carcinogenic.

The comment further states that a "recognized international expert in oncology" concluded that in consideration of the findings in the NCI report and those obtained by himself, "there is obviously wide species, strain, and sex variation both in the incidence of spontaneous tumor of the liver and kidney and in the response of these organs to chloroform." The comment claims that such a conclusion is supported by an opinion expressed by Dr. Grasso in a talk entitled "Evaluation of the Hepatoma in the Rodent in Carcinogensis Bioassay" summarized in BIBRA, 1975 ("The Value of the Mouse in Carcinogenesis Bioassay" summarized i- ed that there is considerable disagreement on the diagnosis of hepatic nodular lesions.

The Commissioner views the conclusions expressed in the comment as relying on the finding that, in studies of three mouse strains, male and female mice showed a sex-linked difference in ability to metabolize chloroform. The Commissioner does not agree that this forms an adequate basis for rejecting the mouse as a useful experimental animal, especially since the work of Hill *et al* indicates that this variability exists not only between sexes but also within the same sex among different strains of the same species. Since these authors cite findings in humans of large interindividual difference in the disposition of commonly used drugs—differences which they attribute to genetic variability—it is not surprising that chloroform toxicity would be variable in the same species as well.

The Commissioner points out that the NCI report observes the variation in species and sex in the incidence of spontaneous tumor of the liver and kidney, and the response of these organs to chloroform. The report notes that the Osborne-Mendel strain was selected by NCI because it was reported to be sensitive to the carcinogenic effects of carbon tetrachloride (CC14). The question of genetic drift within a strain might also be a factor since the positive control (CC14) produced a relatively low response (less than 5 percent with hepatocellular carcinomas). Thus, if anything, the Osborne-Mendel rats used in the NCI studies appear to be less sensitive to the hepatocarcinogen than those reported in the literature.

The Commissioner recognizes that there is disagreement among pathologists on diagnosis of lesions, including hepatic nodular lesions. However, proliferative changes and neoplastic lesions are discussed in considerable detail on pages 32–37 and 40 of the NCI report. The critique submitted by the comment provides no new information that would negate the effects discussed in the pathology section of the NCI report. (41 FR 26842)

2. *Positive Versus Negative Results.* Testing of chemicals for valid negative results may be used to evaluate the evidence only if they are derived from tests which used both sexes of each species tested, exposed for their lifetime to a suitable dose range of the test material, with appropriate controls (WHO Tech. Rept. 220, p. 8; Mrak Commission, p. 486–87). As the Ad Hoc NCI Committee report recommended to the Surgeon General of the United States:

4. No chemical substance should be assumed safe for human consumption without *proper negative lifetime biological assays of adequate size.* The minimum requirements for carcinogenesis bioassays should provide for: adequate numbers of animals of at least two species and both sexes with adequate controls, subjected for their lifetime to the administration of a suitable dose range, including the highest tolerated dose, of the test material by routes of administration that include those by which man is exposed. Adequate documentation of the test conditions and pathologic standards employed are essential. (Emphasis supplied) (P. 1)

However, as the following discussions make clear, OSHA is concerned not about negative test results in species other than the species in which the substance created positive carcinogenic activity, but rather additional negative test results in the species that has been reported as positive in other tests. This is so because, as pointed out, known carcinogens in humans are not necessarily so in all species of test animals or even consistently so.

Likewise, positive results in tests with experimental animals, if obtained under sound experimental conditions and with proper statistical confirmation, should generally supersede negative results, both because of the aforementioned insensitivity of laboratory bioassays conducted with limited numbers of animals, which may frequently lead to false negative results, and also because of interspecies differences in susceptibility. For example, in 1970, the Ad Hoc NCI Committee's report to the Surgeon General recommended that:

5. Evidence of negative results, under the conditions of the test used, should be considered superceded by positive findings in other tests. Evidence of positive results should remain definitive, unless and until new evidence conclusively proves that the prior results were not causally related to the exposure. (P. 1)

FDA appears to accept this view. In banning the use of chloroform, FDA stated:

E. The comment contends that FDA has never made a determination that a substance is carcinogenic on the bases of a single unreplicated study where there are contradictory data, and it refers to saccharin, where the studies produced conflicting test results, as an example.

The Commissioner advises that the reference to saccharin is neither analogous nor applicable to the chloroform toxicity and carcinogencity bioassays relied upon in this action. Thus far, the results of studies using saccharin have been inconclusive; additional studies are ongoing. The results of the NCI studies are conclusive. In addition, the studies submitted by CTFA were conducted at lower dosages than those reported by NCI. The lack of sensitivity of the current carcinogenesis bioassays in rodents is well recognized. Thus the positive finding with chloroform should be given greater weight than studies at lower dosages using smaller numbers of animals.

Moreover, FDA stated:

• • • negative evidence in experimental animals, such as reported in some of the studies submitted by CTFA, does not exclude the potential human carcinogenicity of a substance. The Commissioner is of the opinion that the risk to humans through frequent and long-term exposure to a substance in human drugs and cosmetics that has been shown to be an animal carcinogen is contrary to the public health unless the benefit of such exposure clearly outweighs the risk. (41 FR 26844)

And, it should be noted that certain chemicals may be carcinogenic in certain species, including man, but not in others. For example, betanaphthylamine, a known carcinogen in man, monkeys and dogs, is not apparently carcinogenic in rats or rabbits. Hence, positive studies in any mammalian species will, as a general rule, always supersede negative findings in another species. (UICC 1969, p. 18; NCI, 1970, p. 2; NCAB, report, p. 9)

Thus, OSHA believes that, as a practical rather than a theoretical matter, positive animal data should supersede negative human data, in general, because of the inherent defects in such human studies, as pointed out above. Moreover, in the case of DES, OSHA is unaware of any data indicating that women who took DES during pregnancy (with the possible exception of those with gonadal dysgenesis) have any greater risk of contracting cancer than women who have never been exposed to the chemical. Yet, DES is unquestionably a human carcinogen in terms of at least the exposed female offspring. Thus, humans may be exposing themselves to potential carcinogens that may affect, and appear in, only future generations, at that point a matter which is irreversible even in terms of reduction of exposure. But, as in the case of all known human carcinogens (with the possible exception of arsenic and benzene), DES had been regarded for years as positive, for carcinogenic activity, by all routes of administration, in test animals, including the mouse, rat, hamster and the squirrel monkey.

3. *Testing at High Doses.* The testing of chemicals at constant high exposure levels, at or approaching the maximum tolerated dose level, is not inappropriate and is indeed required to overcome the statistical insensitivity of laboratory bioassays conducted with the limited numbers of animals that can be handled in practical laboratory conditions (WHO Tech. Rept. 220, p. 9; Mrak Commission, p. 487; UIAC 1969, p. 17). As the NCI Ad Hoc Committee's report to the Surgeon General stated:

• • • bioassay methods have remained tools of low sensitivity, capable only of detecting the highest peaks of carcinogenic activity. The factor which limits bioassay sensitivity is usually the small number of test animals used. If the bioassay design has a low probability of detecting carcinogenic effects produced by hazards at levels comparable to those present in environmental samples, then tests at such levels are wastes of time, effort and money. The need to test levels higher than those found in the environment is thus founded. (P. 7)

Regulatory agencies have agreed. The Administrator of EPA stated in *In Re Shell, supra:*

High doses are administered in animal tests, not because the researchers seek to correlate animal response levels to humans, but because with a limited number of animals

this methodology is necessary to determine gross effect. Consequently, a substance that will induce cancer in experimental animals at *any* dose level, no matter how high or low, should be treated with great caution. (Footnotes omitted) (39 FR 37268)

Again, in *In Re Velsicol*, EPA addressed this issue and stated:

Some interest has focused on the high dose levels given to laboratory animals as opposed to the much lower levels encountered by man in the environment, the supposition being that the lower doses naturally encountered may not be dangerous. However, there is not any evidence to indicate that there is a minimum dosage of any known carcinogen below which it does not have a carcinogenic effect. There does not appear to be a relationship between the dose level of a carcinogen on the one hand and, on the other both the percentage of the total of persons or animals exposed who get cancer and the latency period of the disease. High doses in animal experiments are thus justified, and indeed necessary, because the comparatively small numbers of animals necessarily involved in the experiments make it very difficult at least to test for positive results at lower doses.

Testing at * * * relatively high doses is now generally regarded as essential to the attempt to reduce the gross insensitivity imposed on tests by the small size of animal groups routinely tested, such as 50 or so rats or mice per dose level per chemical, compared with the millions of humans at presumptive risk * * *.

To illustrate the insensitivity of conventional animal test systems, assume that man is as sensitive to a particular carcinogen as the rat or mouse. Assume further that this particular agent carries a risk of producing cancer in 1 of 10,000 humans exposed; this would result in approximately 20,000 cancers in the United States population. Then the chances of detecting this in groups of 50 rats or mice, tested at ambient human exposure levels, are very low. Indeed, samples of 10,000 rats or mice would be required to yield 1 cancer over and above any spontaneous occurrences; for statistical significance, perhaps 30,000 rodents would be needed.

Moreover, there exists the problem that for particular chemicals, human beings may be far more sensitive than laboratory animals. For example, thalidomide produces teratogenic effects in man at a dose level that is 1/60 of that needed to produce that effect in mice, 1/100 of that for rats, 1/200 of that for dogs, and 1/700 of that for hamsters. (41 FR 7575)

And again, FDA in eliminating chloroform from drugs and cosmetics stated:

b. The comment also argues that the dosage in the NCI studies was excessive and thus does not support the contention of risk to humans. Noting that the NCI report states that the methodology used in their studies differs from that which is currently used by NCI, the comment states that the most serious defects in the methodology used are the inadequacy of the subchronic toxicity study to determine the maximal tolerated dose (MTD) and one-half MTD, and the failure to employ a meaningful definition of MTD. The comment further states that had a proper and reliable subchronic study been conducted, employing liver and renal function measurements as well as histological assessment of the effects of chloroform upon the liver and kidney, it would have been found that the dose levels used were too toxic. In support, the comment notes that in the NCI rat study, the dose levels had to be reduced after 22 weeks of treatment because the lethal consequences were too great. The comment also cites in support a short term study conducted at Bio/dynamics Inc. at dosage levels of 60, 120, 240, and 480 milligrams/kilogram and with the same strain of mice as that used in the NCI study. In the Bio/dynamic Inc. study both males and females had poor tolerance to the chloroform and at the 480 and 240 milligrams/kilogram levels most of the mice died.

It is the Commissioner's opinion that the growth and survival curves as plotted for the mice in the NCI report reveal no significant effect on growth from the dosages administered, and only in the high-dose level female mice is there an effect seen on survival. However, this effect was observed late in the study, when the death rate showed a sudden increase after the 70th week. The Commissioner therefore concludes that the dosages in the NCI mouse study conform to the standard generally accepted for an MTD to be used in carcinogenicity studies.

In the NCI rat study, it is true that the survival rate for chloroform-treated rats was lower than that for control rats.

However, in the Commissioner's view the high dosage level for male rats appears to conform to standards for MTD when the first 90 days of the growth curves are examined. The comment's objection regarding excessive dosage (greater than MTD) would apply only to female rats. In this regard the Commissioner notes that the statement in the comment that dosage levels employed had to be reduced after 22 weeks because of lethality applies only to the female rats. Despite the reduction in dosage, the survival curves show a consistently lower survival rate. However, the Commissioner emphasizes that there was no increase in tumors reported for these animals. Rather, it was only in the male rats that an increased incidence of renal tumors was reported.

The comment also points out that the ratio of tumor-bearing animals to animals involved in all chloroform treatment groups is less than that found in both male and female matched control groups. This observation, however, is noted and described by NCI in their report as not significant. Moreover, the Commissioner believes the distribution of other than kidney tumors to be normal. Aside from this, the comment disregards the dose-related time of tumor onset. The CTFA analysis further states that "* * * data for the female groups indicate that chloroform treatment may have actually exerted beneficial effects." Obviously, the lethal effects cannot be viewed as beneficial. Finally, the Commissioner notes that in the case of male rats where dosage would appear to conform to the generally accepted standard for carcinogenicity studies, definite evidence of kidney carcinogenicity appeared. (41 FR 26842)

4. *Species or Organ-Specificity.* In experimental carcinogenesis, the type of cancer seen is often the same as that recorded in human epidemiological studies (e.g., bladder cancer in man, monkeys, dogs, and hamsters with beta-naphthylamine). In other instances, however, a chemical will induce neoplasms at different sites in different animal species (e.g., benzidine, which induces hepatic carcinoma in the rat, but bladder carcinoma in man; or chloroform, which induces hepatic carcinoma in the mouse, but kidney carcinoma in the rat) (IARC Monographs, Vol. 1, p. 10; 41 FR 15026; NRC Pest Control, Vol. 1, pp. 74–82). Thus there can be no presumption that the organ affected in animal experiments would necessarily be that at risk in man. And, in *In re Shell* the EPA Administrator further stated:

Most carcinogens are also not organ-specific. In a survey by Dr. Tomatis of 58 compounds known to produce liver tumors in mice, 40 also induced tumors in a variety of other organs. Furthermore, chemically induced tumors in one species need not appear in the same organ in other species. Thus, a carcinogen which induces liver tumors in mice might, for example, produce mammary cancers in rats and lung tumors in men. (39 FR 37268)

5. *Statistical significance.* For adequate demonstration of carcinogenicity of a substance in test animals, it is generally necessary that the increased incidence of neoplasms in one or more of the experimental groups should be evaluated statistically for significance (NCAB Report, p. 5; Mrak Commission Report, p. 465). This requires that the size of the experimental groups be adequately large to permit statistical evaluation (Mrak Commission Report, p. 465; UICC 1969, p. 17).

In contrast to the five (5) points discussed above, on six (6) other issues discussed below (6-11), the opinions of scientific experts appear to be less fully in agreement, and OSHA takes cognizance of the areas of scientific debate in determining the weight to be placed on different types of evidence. However, for the reasons stated in the following discussions, OSHA believes that responsible public rulemaking and prudence concerned with protecting the health of American workers mandate the decisions reached therein.

6. *How much weight should be placed upon the incidence of benign tumors in animals as an indication of potential carcinogenic hazard in man?* There are well-established morphological and histological criteria for distinguishing between benign and malignant tumors, and there is substantial agreement among scientific experts that the occurrence of tumors in advanced stages of cancer—invasion of adjoining tissue and metastasis to other organs—is an unequivocal predictor of carcinogenic hazard to man. Malignant tumors are those that display these characteristics of invasion and metastasis, or have the capacity to do so, whereas benign tumors are those which are judged by experts to lack this capacity (NCAB Report, p. 3). Scientific opinion has varied on the issues of whether substances which induce benign tumors only should be characterized as carcinogenic, and whether they should be regarded as posing a potential carcinogenic hazard to man. Historically, a distinction was drawn. For example, the FDA Panel on Carcinogenicity in 1969 stated:

* * * a carcinogen is a substance that when administered by an appropriate route, causes an increased incidence of malignant tumors in experimental animals as compared with a control series of untreated animals * * *. The occurrence of benign tumors only would not classify an agent as a carcinogen. (FDA Panel Report, pp. 419–420)

The Panel pointed out that:

The occurrence of metatases provides an unequivocal demonstration of malignancy. There are however, many tumors induced experimentally that are invasive and are classified as malignant, that metastasize only rarely during the average experiment. The absence of metastasis, in view of most pathologists, does not rule out the diagnosis of malignancy. (FDA Panel Report, p. 420)

This position was also supported in the 1959 report of the NRC Food Protection Committee:

The general term "cancer" refers to the development of all kinds of malignant tumors. This term is not applied to nonmalignant tumors * * *. It is recognized, however, that progression from benignancy to malignancy may occur. (NRC, 1959, p. 5)

The FDA Panel did, however, note that:

* * * benign tumors may cause death in man and animals without ever undergoing malignant transformation. The induction of a benign tumor is, itself, therefore, an indication of a serious adverse reaction. There can be no doubt from a survey of experimental studies that benign neoplasms are often precursors of malignancies * * * (and) it would be wise to take serious note of the occurrence of benign neoplasms in experimental studies * * *. (FDA Panel Report, p. 420)

However, in more recent times, the considerations that benign tumors are hazardous without progressing to malignant stages and that benign tumors are often precursors to malignant tumors have led other expert agencies and committees to be more cautious in terms of exposing man to potential carcinogens. For example, the Technical Panel on Carcinogenicity of the Mrak Commission stated:

* * * the majority of the Panel recognizes that benign tumors may become malignant. The Panel is unaware of the existence of any chemical which is capable of inducing benign tumors only, which is to say, in the light of present knowledge, all tumorigens must be regarded as potential carcinogens. Thus, the majority of the Panel accepts tumorigenicity as an index of potential carcinogenicity. (Mrak Commission Report, p. 466)

In a discussion of the Litton-Bionetics study sponsored by NCI, the Technical Panel stated:

The end point employed in the study was tumors. This term was used to include the benign and the malignant neoplasms and those neoplasms whose malignancy could not be ascertained on the basis of histomorphology alone * * *. This use of the term "tumor," in the opinion of the panel, is both useful and admissible for the purposes of quantiating chemical carcinogenicity in animals. Its admissibility is based upon two facts: (a) No adequately tested chemical has been found to produce only benign neoplasms and, (b) a substantial percentage of benign-appearing tumors in mice, has been demonstrated ultimately to eventuate in cancer. (Mrak Commission Report, p. 482)

Other reports as well support the position of considering the occurrence of benign tumors to be evidence of carcinogenicity. The World Health Organization Report in 1961 stated:

In the assessment of the carcinogenic risk it is not considered relevant whether the tumor is benign or malignant since the conversion of the first to the second must be regarded as possible. (WHO Tech. Rept. 220, p. 16)

The Ad Hoc Committee that reported to the Surgeon General in 1970 recommended that:

* * * The implication of potential carcinogenicity should be drawn both from tests resulting in the induction of benign tumors and those resulting in tumors which are more obviously malignant. (NCI, 1970, p. 1)

In the report of the Ad Hoc Committee, the earlier definition of the FDA Panel was specifically discussed, and the Ad Hoc Committee stated:

The assessment of the carcinogenic activity of a chemical depends on a variety of parameters. These include not only the total numbers of tumors induced but also their multiplicity, latent period, morphologic type, and degree of malignancy. The induction of tumors diagnosed as benign as a result of treatments has been interpreted by certain groups in the past as not sufficient to demonstrate a "carcinogenic" effect. This is a dangerous position since few, if any, substances have produced only benign tumors and no malignant ones when properly and repeatedly tested. (NCI, 1970, p. 6)

In the report of the WHO Expert Committee in 1964 on "Prevention of Cancer" precancerous lesions in animals were discussed:

In the thinking of most experimentalists the induction of a benign tumour represents the production of neoplasia. Most would feel that this is an indication of carcinogenicity although it is usual to continue studies until morphologically malignant tumours have appeared. There are few studies on record in which only benign tumors are recorded (the neurofibromas induced by ergot appear to be such an instance). In the majority of experimental studies with epithelial tissues, the induction of a benign tumor is merely a stage in the subsequent occurrence of a malignancy. (WHO Tech. Rept. 276, p. 12)

A World Health Organization report on "Principles for the Testing and Evaluation of Drugs for Carcinogenicity" ("WHO Tech. Rept. 426"), published in 1969, stated:

The response of test animals to carcinogens may take one of several forms: (1) an increased incidence of one or more of the tumor types noted in the controls; (2) the occurrence of tumors earlier than in the controls, without increased incidence; (3) the development of types or tumor not seen in the controls (this may or may not be associated with an overall increase in the number of tumors seen in the controls; and (4) a multiplicity of tumors in individual animals, the incidence in terms of tumor-bearing animals being the same. Furthermore, the tumors seen may be benign or malignant, or tumors of both categories may be present. (WHO Tech. Rept. 426, p. 19)

The International Agency for Research on Cancer (IARC) took a similar position:

The qualitative nature of neoplasia has been much discussed. Many instances of carcinogenesis involve the indication of both benign and malignant tumors. There are few, if any, recorded instances in which only benign tumors are induced; their occurrence in experimental systems is usually indicative of eventual malignancy. (IARC Monographs. Vol. 1, p. 10)

And a decision of the Administrator of EPA in suspending two pesticides in *In Re Shell, supra*, is noteworthy. He stated, citing the above mentioned report of the IARC:

The once significant distinction between tumors and cancers, or between tumorigenic and carcinogenic substances has lost much of its validity with the increasing evidence that many tumors can develop into cancers. Thus, for purposes of carcinogenicity testing, they should be considered synonymous. Similarly, the distinction between benign and malignant tumors, while important to the individual host animal, is not a reliable indicator of carcinogenicity, for in the thinking of most experimentalists, the induction of a benign tumor is merely a stage in a subsequent occurrence of a malignancy. (39 FR 27267)

In addition, one recent committee reports the following position:

The carcinogenicity of a substance is established when the administration to groups of animals in adequately designed and conducted experiments results in increases in the incidence of one or more types of malignant neoplasms (or a combination of benign and malignant neoplasms) in the treated groups as compared to control groups maintained under identical conditions but not given the test compound * * *

The occurrence of benign neoplasms raises the strong possibility that the agent in question is also carcinogenic since compounds that induce benign neoplasms frequently induce malignant neoplasms. In addition, benign neoplasms may be an early stage in a multi-step carcinogenic process and they may progress to malignant neoplasms; also, benign neoplasms may themselves jeopardize the health and life of the host. For these reasons, if a substance is found to induce benign neoplasms in experimental animals it should be considered a potential human health hazard which requires further evaluation. In experiments where the increased incidence of malignant neoplasms in the treated group is of questionable significance, a parallel increase in incidence of benign tumors in the same tissue adds weight to the evidence for carcinogenicity of the test substance. (NCAB Report, p. 5)

It is plain from the above quotations that the scientific discussion is not concerned with the significance of benign tumors, but rather with the precise degree of weight that should be placed upon the results of an experiment in which a substance induces only tumors that are authoritatively classified as benign in the test animals. Since such instances are acknowledged to be rare (IARC Monographs, Vol. 1, p. 10; WHO Tech Rept, 276, p. 12; NCI, 1970, p. 6; Mrak Commission Report, pp. 466, 482), the issue may be somewhat academic. However, if such a case should arise before OSHA in regulatory decision-making, the Agency proposes to place as much weight on an experiment in which only benign tumors are observed, as upon experi-

ments in which both malignant and benign tumors are induced.

7. *How much weight should be placed on the induction of a type of tumor which occurs spontaneously in untreated animals?* There has been some debate in recent years as to the amount of weight that should be placed on experiments in which administration of a compound merely increases the frequency of a type of tumor which occurs spontaneously in untreated control animals of the species and strain involved in the test. Some would argue that such compounds should not be classified as carcinogenic, but merely as "augmenting" or "enhancing" agents. However, such a view is not supported by the expert committees which have reviewed this problem:

> For present practical purposes, no distinction is made between the induction of tumors and the enhancement of tumor incidence, although it is noted that there may be fundamental differences in mechanisms that will eventually be elucidated' (IARC Monographs, Vol. 1, p. 10)

and:

> • • • it is not possible to differentiate clearly between initiating agents, promoting agents, and certain modifying factors. Any factor or combination of factors which increases the risk of cancer in humans is of concern regardless of its mechanism of action. (NCAB Report, p. 2)

Ineed, if a species of animals has a very low or zero spontaneous incidence of tumors at various sites, this may indicate that it is resistant to the induction of tumors at these sites by carcinogens, and hence would be unsuitable as an experimental subject. It is for this reason that the use of positive controls in carcinogenesis bioassays is recommended by some expert committees (Mrak Commission Report, p. 467).

A more substantial argument that has been raised is that certain animal strains may be inappropriate for testing because of high and variable spontaneous incidence of tumors in one or more organs. This argument has been made with particular reference to liver tumors in certain strains of mice but has also been made in reference to lympho-sarcomas in mice, and certain other tumors. The NCAB Report cautions against unequivocal reliance on:

> [b]ioassays employing inbred strains of animals which develop high incidences of particular tumors in the untreated state. In some of the studies the particular characteristics of the animals and the results obtained may require additional evaluation—in other instances, such well controlled test systems may be quite satisfactory for the establishment of carcinogenicity of an agent. (NCAB Report, p. 6)

The other expert committee reports cited above, however, expressed no such reservations, merely emphasizing that the spontaneous incidence of tumors be carefully recorded (Mrak Commission Report, p. 465; UICC 1969, p. 17), and in some cases recommending the use of genetically inbred strains with known spontaneous tumor incidence for specific bioassay purposes (UICC 19, p. 16; NAS Principles for Evaluating Chemicals, p. 135; FDA Panel, p. 422). Where the spontaneous incidence of tumors is high or even 100 percent, reliable inferences of carcinogenicity can be drawn from a decrease in the latency periods or an increase in the number of tumors per animal (IARC Monographs, p. 10; FDA Panel, p. 420). In such cases, the emphasis that the study be "well controlled" (NCAB Report, p. 6) is important since the incidence of spontaneous tumors may depend on age or other factors, which therefore must be maintained the same in control and treated groups.

Indeed, recent studies of the mechanisms of cancer induction and their implications for dose-response relationships have suggested that animals with relatively high spontaneous tumor incidence may in fact be *more* appropriate for assaying potential carcinogens than animals with low or zero spontaneous incidence:

> One practical implication of the fact that different carcinogens share many mechanistic steps is that enhancement of certain carcinogenic processes may have a more readily detectable effect on cancer incidence in animals with high background levels of all other carcinogenic processes. Therefore carcinogenicity tests of various substances should possibly include tests on high-spontaneous incidence strains or experiments to see whether the test substance enhances the carcinogenic effect of a standard carcinogen. (K. S. Crump, D. G. Hoel, C. H. Langley, and R. Peto, *Cancer Research*, 36:2977, 1976)

Accordingly, OSHA proposes to interpret the results of experiments showing increased incidence of tumors in treated animals as positive evidence of carcinogenicity, regardless of the spontaneous tumor incidence, provided that the experiments are sufficiently well controlled and the increase in incidence is statistically significant. However, it may be appropriate to place less weight on an experiment conducted with an animal strain in which the spontaneous tumor incidence is relatively high. For example, an increase in tumor incidence from 1% to 21% would appear more biologically significant than an increase from 50% to 70%, even if both were equally significant in the statistical sense. It should be remembered that if only very resistant strains are used, some substances that may be carcinogenic in susceptible humans may be missed.

8. *Which routes of exposure of experimental animals are to be considered appropriate for extrapolation to man?* The NCI Ad Hoc Committee recognized that exceptions to the validity of qualitative extrapolation from data on carcinogenic effects on animals to predict potential hazard for man might be considered "where the route of administration is grossly inappropriate in terms of conceivable human exposure." (NCI, 1970, p. 1). The National Cancer Advisory Board Subcommittee similarly expressed reservations about the unequivocal interpretation of:

> [b]ioassays in which the test compound is given by unusual routes of administration [such as bladder implantation] and there is reason to believe that the tumors that occurred may not be due to a specific effect of the test compound. (NCAB Report, pp. 6–7)

However, the Subcommittee continued:

> This does not mean, however, that substances should only be tested in animals by the same route of administration as pertains to human exposure (*ibid.*).

In cases where the test compound is absorbed by the experimental animals and is circulated systemically, giving rise to tumors at sites other than the point of application, it seems reasonable to regard the route of administration as irrelevant to weighing the potential risks to man. This principle was specifically enunciated by the National Cancer Institute in its report in the "Carcinogenesis Bioassay of Trichloroethylene" (NCI Carcinogenesis Tech. Rept. Series No. 2, May 31, 1976):

> Trichloroethylene was administered by gavage in this study while the main human exposures are by inhalation of vapors and by ingestion through contaminated water and food products. The selected route of exposure is considered relevant to all modes of human exposure because trichloroethylene is readily absorbed and distributed to all organs following ingestion or inhalation. This has been shown in several species, including the rabbit (Gasq, 1936), the dog (Barrett and Johnston, 1939), and the guinea pig (Fabre and Truhaut, 1952). The fact that in this study tumor induction occurred in the liver indicates that trichloroethylene was absorbed and that systemic exposure of tissues occurred. (NCI Tech. Rept. Series 2, p. 41)

In cases where tumors are induced in experimental animals only at the site of administration of the substance, it becomes important to evaluate the appropriateness of the route of exposure to that likely to occur in occupational situations. OSHA intends to consider each such case on its merits, subject to the following guiding principles:

> (1) oncogenic effect resulting from dermal, inhalation, injection (with tumors at distant sites) and oral exposure (including gavage or intratracheal instillation), shall be regarded as directly relevant to occupational exposure, except in special circumstances;
>
> (2) carcinogenesis resulting from injections or implantations, in which the tumors are induced only at the site of application, shall generally be regarded as irrelevant to occupational exposure, except where the substance is distributed systemically or in other special circumstances.

OSHA draws attention to this specific part of the proposal and invites public comment on its proposed conclusions.

9. *How much confirmation of positive results is necessary?* For the reasons stated above, positive results in tests with experimental animals, if obtained under sound experimental conditions and with proper statistical confirmation, should in general, supersede negative results, including those in humans, as pointed out. In particular, positive findings of carcinogenicity in one animal species should generally outweigh negative reports in another, in relation to human application (UICC, 1969, p. 18; NCI, 1970, p. 2, NCAB Report, p. 9).

Nevertheless, OSHA recognizes that "false positive" results may arise occasionally, both through statistical ac-

cidents and honest errors in the conduct of single experiments. Accordingly, OSHA recognizes that much greater weight should be attached to positive results that have been replicated in another study than in a single unconfirmed result. As the National Cancer Advisory Board expressed the situation:

> Such increases [in neoplasms in experimental animals] may be regarded with greater confidence if positive results are observed in more than one group of animals or in different laboratories. The demonstration that the occurrence of neoplasms follows a dose-dependent relationship provides additional evidence of a positive result. (NCAB Report, p. 5)

While recognizing the importance of a single positive result as a warning flag, the Agency believes that it would not serve the interest of responsible public rulemaking to impose major, cost intensive regulatory requirements on the basis of unconfirmed, and possibly unreproducible, results. Following the guidance of the NCAB Subcommittee, which emphasized in the above-quoted passage and elsewhere that varying degrees of confidence can be attached to positive results, OSHA proposes to establish a three-tier system of classification for those toxic substances that are found in the American workplace. In general, as is more fully discussed below, Category I toxic substances are those whose carcinogenicity, as defined, has been determined in humans or in two or more mammalian species of test animals or in one species if the results of that study have been replicated. Category II toxic substances are those whose carcinogenicity has been reported but the evidence for some reason is only suggestive, as defined, or positive in one species, but not yet replicated. Category III toxic substances are those for which the evidence is inadequate to raise any concern regarding carcinogenicity or where the evidence consists of animal data in a single species that is less than suggestive. As pointed out, OSHA is also proposing a classification for those substances that might be classified as one of the 3 categories except for the fact that they are not found in American workplaces (Category IV toxic substances).

OSHA recognizes that there are other factors involved in carcinogenicity tests which affect the degree of confidence in the results (e.g., choice of strain, spontaneous tumor incidence, duration of experiment, survival, intensiveness and competence of pathological examination, etc.). In addition, OSHA may require detailed review of each experiment, including, where necessary, independent pathological diagnoses, before classifying each toxic substance. Comments on this aspect of the proposed classification scheme are specifically invited.

These principles appear to be closely aligned with past actions of FDA and EPA. For example, in *In Re Shell supra*, the Administrator of EPA stated:

> Some witnesses also suggested that carcinogens can be species-specific—that is, a chemical substance might affect mice but not any other species, including man. This is theoretically possible. But of the thousands of compounds tested the record indicates that this effect has been suggested for only one of them, and even this single exception has been seriously challenged. I therefore will rely on the conclusion of such organizations as the International Association for Research on Cancer, which have rejected species-specificity as unsubstantiated
>
> If carcinogens are not species-specific, it logically follows that the demonstration of carcinogenic effect in more than one species is not absolutely necessary for a finding of carcinogenicity.
>
> • • • • •
>
> This evidence of carcinogenicity [in the mouse] is supported by additional, although not definitive, evidence that Aldrin-Dieldrin has increased the incidence of tumors in rats. Dr. Upton, a recognized cancer expert, has testified:
>
> In safety testing of carcinogens today we are concerned with one question: Does exposure to the test agent result in a significant induction of tumors in exposed populations as compared to controls? If so then the test agent has elicited a carcinogenic response and must therefore be considered potentially hazardous to human health. Whether the agent actually is a *sine qua non* of the observed response or merely enhances a virus or some other factor found in the host animal is irrelevant unless and until we know that similar factors are not also found in man. Until we have such knowledge, we have no basis on which to make distinctions between "carcinogens" and "co-carcinogens" and "causative agents" versus "enhancing agents".
>
> Given this lack of knowledge concerning mechanisms, I believe that a carcinogenic reaction in any species of test animal must be considered sufficient to describe the test compound as a carcinogen and so a threat to human health. I consider that a similar reaction in a second mammalian species is a confirmation of the carcinogenicity of the test agent but it is not necessary before a finding of carcinogenicity and threat to human health can be made; and negative results in a second or even third species of test animal do not in my mind establish that the test agent is not a threat for human beings. Given the variation in human susceptibility to carcinogens, I believe it unreasonable to ignore a finding of carcinogenicity in any mammalian test species when considering possible effects on human health. (Emphasis added) (39 FR at 37269–70)

10. *Can "safe" or "no-effect" levels be set for exposure to chemical carcinogens?* Toxic effects, and biological effects in general, are assumed on the basis of much experience to occur above a certain "threshold" or "no-effect" level of exposure to the causative agent or agents. For many such effects, thresholds may theoretically occur for specific individuals as well as for defined populations at risk, even though thresholds for specific individuals may vary substantially within a population. The relationship between dose and response and knowledge of the underlying biological stages leading to the effect in question provide the basis for estimating such thresholds for defined populations. Safety factors are then applied to give additional assurance that the estimated threshold is not too high.

For many chemical carcinogens, identified either by means of studies in man or animals, a relationship between dose and response has been found to exist. The nature of the relationship is generally for the response to increase with increasing dose, although in some carefully studied cases this relationship has been found either not to exist or to be opposite to that usually found (the response is greater at lower doses). In comparable test systems, chemical carcinogens can vary in the responses they elicit by as much as a factor of 10^7 (WHO Tech. Rept. 546, p. 11).

The incidence of tumors and the period of latency can be related to dose, and because any individual has a finite lifetime an individual threshold may exist by virtue of the fact that the latency of the disease may be so long that it exceeds the individual's lifetime. Also, in light of increasing evidence that cancer originates from a single cell a threshold may exist for the particular affected cell; however, a large number of factors—age, sex, nutritional status, and health, to name a few—can affect individual susceptibility, and there is a large number of types of cells that can give rise to cancer. Thus, there is no means of predicting an individual threshold, even if they do indeed exist.

It might be thought that on the basis of general experience with other toxic effects, no-effect levels for a defined population could be set for chemical carcinogens by means of extrapolation from observed dose-response relationships. However, the variation among individual susceptibilities to cancer is extremely large, making it very difficult to place any confidence in observed no-effect levels in animals or in defined human populations for which individual variations are small in comparison. Furthermore, the underlying biological events by which cancer is initated and progresses are not well understood, and on the basis of what is known the existence of thresholds for chemical carcinogens has been questioned because of:

> (1) the self-replicating nature of the cancer cell.
>
> (2) • • • work • • • which has been interpreted to indicate summation of irreversible effects in carcinogenesis • • •.
>
> (3) evidence from experiments on tumor initiation and promotion in skin carcinogenesis indicating lasting change induced by one tumor-initiating event.
>
> (4) the fact that cancer can occur in response to chemicals, even after single doses, long after their disappearance from the body.
>
> (5) the possibility that cancer may result from mutation in a somatic cell (that is, a cell that contains all the necessary genetic materials to life, as opposed to a germ or reproductive cell which contains only half the necessary genetic material. (WHO Tech. Rept. 546, pp. 9, 10)

The nature of the dose-response relationship and the existence of thresholds has been discussed by many expert committees and they are substantially in agreement that dose-response data cannot be used to set no-effect levels for exposure to chemical carcinogens. As early as 1959 the NRC Food Protection Committee stated:

> • • • the possibility exists that doses at "no-effect levels" [observed in experimental studies] do in fact exert carcinogenic

effects but that the effects are too weak to detect with the numbers of animals feasible for routine testing. Such a possible effect, though extremely weak, might become evident in a large population such as, for example, the population potentially exposed to * * * [the substance].

The foregoing * * * supports the view that there is a level of exposure to a carcinogen below which cancer will not be induced in the exposed animal. The practical establishment of this threshold level is, however, complicated by a number of factors affecting, or related to, the carcinogenic process * * *. (NRC, 1959, p. 15)

The Committee also stated:

Information obtainable from dose-response curves prepared from data obtained in animal experiments appears of limited practical use in evaluating carcinogenic hazard for man. The apparent lack of quantitative correspondence in the carcinogenicity of a substance for different mammalian species and the other complicating factors that have been discussed make meaningful extrapolation from the "no-effect" level on the dose-response curve to a "safe level" of use by man currently impossible. * * *. (*Ibid.*, pp. 31, 32)

This view was reiterated by the Joint FAO/WHO Expert Committee in 1961, the WHO Expert Committee in 1964, and in 1969 the Technical Panel on Carcinogenicity of the Mrak Commission, which stated:

The evaluation of carcinogenic hazards for man is based on a judgment of all available information: on bioassay, on toxicologic, metabolic, and pharmacologic studies, on the extent and route of exposure of man, and on epidemiologic studies * * *. The position of this Panel is that the different qualitative and quantitative response of various animal species, including man, to carcinogens make meaningful extrapolation from "no-effect" levels in dose-response studies in animals to man currently impossible * * *. (Mrak Commission Report, pp. 466, 467)

The FDA Panel discussed the quantitative methods available at that time for estimating a "virtually safe dose," particularly the methods proposed by Mantel and Bryan and by Druckrey (N. Mantel, "The concept of threshold in carcinogenesis," *Clin. Pharmacol. Therap.*, *4*, 104–109 (1963); N. Mantel and W. R. Bryan, " 'Safety' testing of carcinogenic agents," J. Nat. Cancer Insti., *27*, 455–470 (1961); H. Druckrey, "Quantitative aspects in chemical carcinogenesis," U.I.C.C. Monograph No. 7, "Potential Carcinogenic Hazards from Drugs," 60–77 (1967); H. Druckrey, R. Preussman, S. Ivankovic, D. Schmaehl, "Organotrope carcinogene Wirkungen bei 65 verschiedenen N-Nitroso-Verbindungen an BD–Ratten," *Z. Krebsforsch 69*, 103–201 (1967). The Panel said:

* * * the only practicable basis for estimating a safe dose is by extrapolation downward from results obtained at some level well above the actual use level. But this extrapolation introduces serious uncertainties, which must be recognized if rational methods of safety evaluations are to be developed. The basic problem is that extrapolation outside the range of observation must be based on generally unverifiable assumptions about the mathematical nature of the dose-response relationship near zero dosage * * *. (FDA Panel Report, p. 432)

And the Panel concluded:

Although it is possible in principle to estimate "safe" levels of a carcinogen, uncertainties involved in downward extrapolation from test levels will usually result in permissible levels that are the practical equivalent of zero. (*Ibid.*, p. 435)

One committee that has been interpreted as differing to an extent on this point from others is the NRC Food Protection Committee of 1969 and 1970. The Committee stated with respect to the evaluation of carcinogenic hazards:

Although there are probably noncarcinogenic dosage levels for an experimental species in which a given compound is carcinogenic, there is as yet no generally accepted way of quantitatively extrapolating dose-response data in predicting a noncarcinogenic level for man. This fact is the principal basis for urging that such compounds be permitted for use in foods only if an explicit judgment has been made that demonstable benefit greatly exceeds the risk. (NRC, 1970, pp. 47, 48)

Despite this situation with respect to cancer, the Committee introduced criteria for toxicologically insignificant levels of exposure to apply generally to substances found in the diet. The Committee stated that:

[t]o provide optimum assurance of public safety within the limitations of capabilities available, toxicological facilities for evaluating safety must be concentrated on environmental situations in which there is a reasonable expectation that exposure to chemicals may cause real hazards. The definition of a "toxicologically insignificant" level simply as one well below an established safe level is too indefinite and too limiting to be of practical value, since it requires in every case the establishment of a safe level by experiment. To insist that nothing can be assumed to be safe without direct experimental toxicological evidence implies that safety must be proved experimentally before the proof of safety can be considered unnecessary. This denies the value of establishing criteria for insignificance. Thus, there is urgent need to arrive at more specific guidelines for estimating dietary levels that can be considered toxicologically insignificant. (NRC, 1970, p. 51)

However, the Ad Hoc Surgeon General's Committee discounted the application of this concept to evaluations of carcinogenic risks. The scientific blue-ribbon Committee recommended to the Surgeon General that:

2. No level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents a "safe level for man" cannot be established by application of our present knowledge. (NCI, 1970, p. 1)

In addition, the Committee recommended that:

3. The statment made in 1969 by the Food Protection Committee * * * that natural or synthetic substances can be considered safe without undergoing biological assay should be recognized as scientifically unacceptable * * *.

The Committee further stated:

It is impossible to establish any absolutely safe level of exposure to a carcinogen for man. The concept of "toxicologically insignificant" levels (as advanced by the Food Protection Committee of the NAS/NRC in 1969; see Appendix II), of dubious merit in any life science, has absolutely no validity in the field of carcinogenesis. (P. 7)

Thus, once a qualitative presumption of carcinogenicity has been established for a substance, any exposure to the substance must be considered to be attended by risk when considering any given population. No exception to this point has yet been demonstrated. OSHA proposes to adopt this principle to establish qualitatively the existence of risk posed by exposure to carcinogens, and hence to justify the classification of substances shown to be carcinogenic in animals at Category I or Category II toxic substances as proposed in the rulemaking. OSHA does, however, recognize that obviously not all individuals contract cancer because of exposure to a carcinogen. Thus, it appears that there may be individual effect levels. However, we have attempted to point out, we do not know who in any exposed population is susceptible and at what levels.

The regulatory decision to treat a carcinogen as having no "safe" or "no-effect" levels is supported by logic and decisions made by OSHA and other regulatory agencies.

First, as pointed out, is our inability, at present, to determine whether humans are more or less sensitive than the test animal in question. In the case of thalidomide, admittedly not a carcinogen but a tetratogen, human were 60 times more sensitive than mice, 100 times more sensitive than rats, 200 times more sensitive than dogs and 700 times more sensitive than hamsters. In the case of inorganic arsenic, a known human carcinogen, no positive results have been reported in any mammalian test animal, including the mouse and rat, although negative results have been. And in the case of beta-naphthylamine, a known bladder carcinogen in man, monkeys and dogs, negative reports have been reported in rats and rabbits. Hence, today it does not appear feasible to predict a quantitative finite "safe" level for a carcinogen to an individual human, let alone for a population, comprised as we are of aggregates of genetically heterogeneous individuals with widely varying predispositions and susceptibilities.

Second, other bodies and regulatory agencies have taken the same position in the past, in addition to OSHA. In 1958, Congress expressed its policy by enacting the "Delaney Clause" which, in general, imposes a zero tolerance for carcinogenic food additives. The clause states:

* * * no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals * * *.

These conclusion were further emphasized, as pointed out, by the expert committee of the World Health Organization in 1961:

* * * It is agreed that no assuredly safe level for carcinogens in human food can be determined from experimental findings at the present time. (P. 5)

In 1960, Secretary Arthur Flemming of the Department of Health, Education, and Welfare testified at the Hearings on Color Additives, Committee on Interstate and Foreign Commerce, House of Representatives that:

> Scientifically, there is no way to determine a safe level for a substance known to produce cancer in animals.

This scientific principle was re-affirmed over fourteen years later by Secretary Caspar Weinberger of the same Department, in a letter dated June 14, 1974 to the Congress objecting to proposed legislation amending the "anti-cancer" or Delaney clause of the Food, Drug and Cosmetics Act. He said.:

> At present the Department of Health, Education and Welfare lacks the Scientific information necessary to establish no-effect levels for carcinogenic substances in animals in general and in man in particular. In the absence of such information, we do not believe that detectable residues of carcinogenic animal drugs should be allowed in the food supply.
>
> • • • • •
>
> • • • It may someday be possible for the Department to establish levels at which residues of carcinogens can safely be tolerated in human food without risk of cancer to humans. Until the necessary scientific data base exists to establish such levels, however, we oppose enactment of legislation such as H.R. 922 or H.R. 1171 to amend or even repeal one or all of the anticancer clauses of the Act. Enactment of such legislation would have no effect on current Department policies since, under the present state of scientific knowledge, the general safety provisions of the Act would not permit this Department to allow detectable residues of carcinogenic animal drugs in human food.

And finally, in the revised NIOSH Arsenic Criteria Document (1975), the Director of NIOSH also stated:

> • • • it is not possible at present to determine a safe exposure level for carcinogens. (p. iv)

The proposal therefore makes clear, as pointed out below, that in regulating a toxic substance that meets the criteria of a Category I toxic substance, the level of exposure set by the standard is not a "healthful", "safe", or "no-effect" level but a feasibility level. The proposal further provides that the Secretary shall determine what levels of employee exposure can feasibly be met.

11. *Quantification.* While OSHA is of the view that "threshold" or "no-effect" levels cannot be set for chemical carcinogens, some have said that it may be desirable to attempt to quantify risk for the purpose of evaluating the expense and level of control considered feasible in view of the risk posed by any given substance. However, because of the previous discussion, it appears that such consideration should apply, if at all, only at the point of considering the feasibility of the regulatory provisions of any given standard—not the risk as determined pursuant to this proposed regulatory framework. Work by Mantel and coworkers (N. Mantel, N. Bohidar, C. Brown, J. Ciminera, and J. Tukey, "An Improved 'Mantel-Bryan' Procedure for 'Safety' Testing of Carcinogens," Cancer Res., *35*, 865–872 (1975) and by N. Mantel and M. Schneiderman, "Estimating 'safe' Levels, a Hazardous Undertaking," Cancer Res., *35*, 1379–1386 (1075) highlight the need to be cautious in estimating the nature of the dose-response relationship for chemical carcinogens. More recent work by Crump *et al.* (K. Crump, D. Hoel, C. Langley, and R. Peto, "Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment," *Cancer Res., 36*, 2973–2979 (1976)) indicates that on the basis of increasing evidence that exposure to carcinogens is additive and that since a large number of carcinogenic substances are known to be present in the environment at low levels, any low dose exposure can be seen as affecting an ongoing process in which progressive stages are shared by chemical carcinogens in general. Thus a mathematical model that incorporates a number of very different biological models of cancer causation shows that the response in terms of the number of individuals at risk within a population will be linear with dose. With respect to the method employed by Mantel to predict risk at low doses the authors state:

> • • • [it] may be valid for a few very special 'indirect' carcinogenic processes, but our arguments suggest that in general it is not correct • • •. (Crump, *et al.*, p. 2978)

and the authors recommend that:

> • • • linear dose-response relationships are likely to be approximately correct for many environmental carcinogens, and this should be publicly agreed for such substances, as it was for radiation 20 years ago. (*Ibid.*, p. 2979)

OSHA invites comments on whether such an estimation should be attempted and, if so, the methods to be employed for a quantitative estimation of risk to be used in the rulemaking process triggered by classification of a toxic substance as a Category I toxic substance. Such a classification will establish required control techniques and also require that permissible levels of exposure be reduced to as low as feasible.

C. SHORT-TERM OR IN VITRO TESTS FOR CARCINOGENS

OSHA is aware that short term and *in vitro* tests for carcinogens are being developed rapidly, take a few weeks at most to complete and yet examine the capacity of a substance to cause mutagenicity, other genetic alterations or neoplastic transformation. Reliance upon the short-term mutagenic tests is based upon the assumption that cancer can be related to genetic alterations and that, therefore, detection of such changes is indicative that such a substance may have cancingenic potential. Mutagenisis tests are very useful as screening tests because they can be conducted quickly and inexpensively. In addition, short term tests have been developed to test the ability of a substance to induce neoplastic transformation of cells that are cultured *in vitro*.

Short term tests use a variety of biological systems, such as bacteria yeast and mammalian cells. These methods are in various stages of development and some of these methods have been more extensively utilized than other ones. To date, the most widely used method appears to be the Salmonella, or Ames, test. This method utilizes several specially constructed strains of Salmonella bacteria to detect mutagenic changes. Rat (or human) liver extracts are used to activate the mutagenic form of the substance being tested. However, although the correlation between positive short term test and animal carcinogenity may be good, the number of validation studies is still small. Therefore, OSHA agrees with the following judgment as to these tests, at the time, set further in the NCAB report:

> A major practical limitation in the bioassay of potential carcinogens is the large number of test animals and the long duration required to obtain results. A number of short-term or in vitro tests are currently under development and appear promising. These include assays for: the induction of DNA damage and repair; mutagenesis in bacteria, yeast, Drosophila melanogaster, or in mammalian somatic cell cultures; and neoplastic transformation of mammalian cells in culture. Other assays that have been employed include the dominant lethal test and studies of chromosonal damage. The latter two tests suffer from the fact that they are frequently non-specific and/or difficult to quantify. Of the various short-term tests, the Ames Salmonella mutagenesis system has been studied the most extensively. Tests based on other in vitro approaches are also being developed.
>
> The intelligent application and interpretation of the in vitro tests must also take into account species variations in factors related to the pharmacologic distribution and metabolism of the parent compound as well as possible species differences in macromolecular repair and host defense mechanisms. A number of approaches addressed to the metabolic aspects are now available, including "host-mediated" mutagenesis assays; the assay of urine and other biologic fluids taken from animals or humans receiving the test compound; the addition of microsomal enzymes and co-factors to the assay system; and the inclusion of specific cells in the assay.
>
> At present, none of the short-time tests can be used to establish whether a compound will or will not be carcinogenic. Positive results obtained in these systems suggest extensive testing of the agent in long-term animal bioassays, particularly if there are other reasons for testing. Negative results in a short-term test, however, do not establish the safety of the agent.
>
> This Subcommittee is enthusiastic about the possible future use of in vitro tests as part of a screening system for potential carcinogens and believes that their further development and validation deserve high priority.

Thus, while these short-term tests appear very promising for the identification of carcinogens, OSHA does not regard them as sufficiently well developed for use as a sole basis for identification of carcinogenic potential. However, OSHA does believe that it is appropriate to give serious regard to a combination of positive results when found both in adequate short-term tests and in experimental animal models. In particular OSHA proposes that the combination of positive results in short-term tests and a positive result for carcinogenesis in a single bi-

oassay in a mammalian test species would provide sufficient evidence for classifying a substance as a Category I toxic material. In this regard, FDA, in banning chloroform stated:

> Regarding the reported findings of Uehleke in the "Ames study," which use a bacterial system, the Commissioner recognizes that rapid progress is being made in the development of mutagenicity test systems. He is aware of a number of reports indicating a mutagenicity carcinogenicity correlation using these test systems. However, a number of "false positives" as well as "false negatives" have been observed in these test systems. Such tests using nonmammalian systems have not been validated for establishing correlations and are not considered an appropriate basis for regulatory actions. (41 FR 26842)

D. MOLECULAR STRUCTURE OR SIMILARITY

Whether chemical similarities between know carcinogens and other untested substances should be used to qualitatively predict the carcinogenic effects of those untested substances, as a matter of regulation, rather than of research, has been debated in recent time.

OSHA is aware that, for many years, priorities for scientific research in testing individual substances for carcinogenic activity have sometimes been set, to a certain extent, by the structural similarity of those substances to be tested to the structural similarities of other substances that have been tested and found positive for carcinogenic activity. This concept has often been referred to as the "structure/function" theory. Many have recognized the distinction between using a structural similarity to predict carcinogenic activity of an untested substance as a basis for setting priorities when actually testing substances on the one hand and using such structural similarity to regulate untested substances that may have a great deal of structural similarity to substances that have been tested and found positive on the other hand. OSHA agrees, at this time, with the Ad Hoc NCI Committee's Report to the Surgeon General that:

> The carcinogenic activity of materials can only be detected by long-term biological tests. At the present time the chemical structure or physico-chemical properties of a compound do not provide a reliable basis for prediction of freedom from carcinogenic activity. Several structure-activity correlations are valuable indicators of the possible carcinogenicity of a compound, but none can be used to classify the compound as non-carcinogenic. Short-term bioassays that determine the effect of certain chemicals on selected biologic targets have not been reliable for prediction of carcinogenic activity. (Pp. 5–6)

Chemicals of many classes and vastly different structures have produced cancer of virtually all organ sites in experimental animals. For some of these chemicals, there are data showing cancer induction in man. OSHA is not aware of any single molecular configuration, structural characteristic, or physical property of chemical carcinogens that can be pinpointed as the crucial cancer inducing element or site. One explanation may be that a substance may be metabolized to a different form when exposed to the test model or man and that metabolite be the carcinogen, rather than the substance itself. However, gross similarities in chemical reactivity and metabolic fate in the host can be identified for many chemical carcinogens. This followed the discovery by the Millers that metabolic conversion of environmental chemical carcinogens can occur in the host with the ultimate formation of the "proximate" or "active" form of the chemical carcinogen.

The history of attempts to identify structure/activity correlations useful for the prediction of carcinogenic capability on the basis of chemical structure is as old as the scientific study of carcinogenesis. Cook, Kennaway, and their coworkers [7] in 1932 were the first to isolate and characterize the carcinogenic polycyclic aromatic hydrocarbons (PAH) in soot. They were unable to identify any unique distinction between carcinogenic and noncarcinogenic PAH. Years later a major step forward in the knowledge of the metabolism of PAH was achieved in 1964 by Boyland and Sims,[8] who demonstrated the formation of epoxidic metabolites of carcinogenic PAH. They, too, were unable to identify the locus responsible for carcinogenic properties. The epochal observation of the Millers [9] in 1968 that all chemical carcinogens that are not themselves chemically reactive must be converted metabolically into a reactive form, and that this reactive form is an electrophylic reagent, provides some hope that a unifying thread for carcinogenesis exists and may someday be found.

The limitations in our current knowledge of carcinogen metabolism which fail to provide a basis for prediction are reinforced, however, by several other categories of data which further cast doubt that structure/activity correlations are a useful tool for regulatory purposes at the present time. These include variations within major classes of chemicals, such as PAH, aromatic amines and amides, and chlorinated hydrocarbons.

In addition, it appears that single substituents can markedly affect carcinogenic potential. As shown by the Millers in 1961, the substitution of a fluorine atom in the 6 position of the K region of 7 methyl-BA had little effect on carcinogenicity, while a fluorine substitution in the 5 position appears to have completely obliterated the carcinogenicity of this compound. The literature on chemical carcinogenesis is replete with myriad instances where a single atom or molecule substituent markedly affects carcinogenic potential.

Finally, it appears that isomers of carcinogenic chemicals may frequently exhibit non-carcinogenic effects. Stearic properties of chemical compounds appear to be of major importance in the ultimate carcinogenic potency of the compound. Non-carcinogenic isomers of chemical carcinogens are common, as for example perylene (non-carcinogenic) and benzo-a-pyrene (carcinogenic). An array of non-carcinogenic isomers exist for the carcinogenic aromatic amine 3'DAB.

That someday structure/activity correlations would be of predictive value for regulation is something that all would appear to hope for. However, in addition to the obstacles listed above, there are the compounding factors of dose dependent variations in metabolic fate, species differences in anatomic and metabolic fate, and the influence of related compounds (summation, synergism or inhibition) upon chemical carcinogens when present simultaneously either in the environment or in the host. Thus, at least at this time, OSHA does not propose to rely upon structural similarities between known carcinogens and other substances to regulate those other toxic substances as carcinogens. Public comment as to this specific part of the proposal is invited. In that regard, such comment may also address whether implementation of the Toxic Substance Control Act might in effect, "moot" this problem by requiring testing based on such molecular or structural similarities.

III. Classification and Regulation: The Proposal

The previous discussions have set forth the necessity of and the rationale for OSHA's proposal to identify, classify and regulate potential occupational carcinogens. It is not intended to duplicate those discussions here. The following sections attempt to explain: (1) the procedural mechanisms which will be utilized to accomplish these goals and (2) the additional rationale and policy considerations, not been already discussed above, regarding the specific requirements that will be mandated by the three individual model standards that are part of these proposed regulations.

The individual model standards include an emergency temporary standard (ETS) to be issued, in general, if the toxic substance meets the criteria for a Category I toxic substance; a proposed permanent standard for such a Category I toxic substance; and a proposed permanent standard for those toxic substances that meet only the criteria for a Category II toxic substance, as defined. The three proposed model standards incorporate OSHA's views concerning which protective provisions are generally the most appropriate to permanently protect employees against exposure to Category I and Category II toxic substances, as defined, and, in the model emergency temporary standard, which protective provisions should be instituted immediately. As a result of this rulemaking, OSHA will promulgate, in final form, models for an emergency temporary standard and for permanent standards for Category I and Category II toxic substances. Except where the unique properties of such a substance

[7] Cook, J. W., Hieger J., Kennaway E. L., and Mayneord W. V. Proc. Roy. Soc. B111 455–484, 1932.

[8] Boyland, E. Sims, P. Biochem. J.; 91 493–506.

[9] Miller, E. C., Miller J. A.; in Molec. Biology of Cancer (H. Busch Edit.) 377–402 Academic Press N.Y. 1974.

warrant departure from any given provision, the model ETS will be issued as the actual ETS when a substance is classified as a Category I toxic substance. Similarly, the model Category I and Category II permanent standards will be issued as the proposal in the subsequent section 6(b) proceedings except where unique properties of the substance under consideration warrant departure from any given provisions. It is OSHA's intention that apart from the unique substance-specific aspects of these standards, the appropriateness of the model permanent standards, resolved in this proceeding, will not be at issue in the subsequent rulemaking proceedings. Once promulgated in this rulemaking therefore, these proposed procedures, identification and classification criteria, and the provisions of the model standards will be consistently applied in future regulatory activity. Of course, the Secretary's decision in the particular final standard will reflect the adequacy of the evidence in the rulemaking record in support of any such deviation, addition or change from the model standard.

This regulatory framework permits OSHA to retain the flexibility necessary for regulating substances of differing toxicological properties while speeding the process of standards development in the important area of control of exposures to potential or proven cancer causing substances.

This proposed set of regulations also provides for a third and fourth category of toxic substances. The third category of toxic substances (Category III), includes those toxic substances for which OSHA had determined that the evidence is insufficient to warrant taking regulatory action insofar as carcinogenicity is concerned. In other words, the proposal requires that OSHA, as a responsible public agency, will affirmatively review the evidence, concerning any substance that meets the definition of a toxic substance, seek public comment and then classify these substances as Category III toxic substances, if warranted. In addition, this action will notify the public, industry and labor of OSHA's position so that attention can be drawn to the important task of reducing employee exposures to those other substances that are or have been identified as Category I or Category II toxic substances.

Finally, the fourth category of toxic substances (Category IV) includes those substances that might meet the definition of a toxic substance except that they are not found in American workplaces. OSHA intends to list these substances in the FEDERAL REGISTER and the Code of Federal Regulations for the convenience of the concerned public. However, OSHA does not intend to review the evidence concerning carcinogenicity at that time. And, as pointed out below, OSHA intends to enter into an agreement with EPA with respect to implementation of the Toxic Substances Control Act so that when or if such substances are permitted to be introduced into the American workplace, OSHA will have ample time to develop a standard regulating exposure to the substance as is warranted by the proposed regulatory program herein.

A. GENERAL

Section 1990.102 sets forth the general definitions for both a "toxic substance" and a "potential occupational carcinogen". OSHA is aware of the difficulties that experts have had in reaching a scientific consensus as to the precise definition of a carcinogen. However, as pointed out above, the definitions herein are viewed, for the purposes of regulation, as reflecting policy decisions, and not solely as decisions of science.

The definition of a toxic substance is intended to include any scientific report of carcinogenicity as pointed out below, and merely meeting the definition would not require by itself that the Secretary initiate standard setting activity. In other words, the term "toxic substance" is intentionally defined to include more substances than the definition of a "potential occupational carcinogen", i.e. any information that is "reported" to meet the definition of a potential occupational carcinogen is sufficient to categorize that substance as a toxic substance. The purpose of this preliminary designation as a toxic substance is to require the Secretary to affirmatively classify the substance, after receiving public comment and reviewing the available information. As described below, the classification category would either require the initiation of standard setting activity or an announcement that the evidence appears insufficient to require regulation of the substance as posing a carcinogenic risk to man.

For purposes of this regulation, a toxic substance will be classified qualitatively as a "potential occupational carcinogen" if it has been found in the American workplace and OSHA believes that it has been shown: (a) to cause, at any level of exposure or dose, as the result of any oral, respiratory or dermal exposure, or any other exposure which results in systemic distribution of the substance under consideration, in the organism tested, an increased incidence of malignant or benign neoplasms, or a combination thereof, in any experimental mammalian species or in humans, or, (b) in a statistically significant manner decreases the latency period between exposure and onset of neoplasm formation in any experimental mammalian species or in humans. In addition, the definition is intended to cover leukemogens and particulate substances such as asbestos. However, it is not intended *per se* to include non-systemic substances which are reported to cause injection site sarcomas.

OSHA is of the impression that a certain number of the "suspect carcinogens" reported by NIOSH are not found in American workplaces. Naturally, therefore, no standard for such a substance will be required and no classification will be made for such substances at this time. Thus, the definition of a "foreign toxic substance" has been provided to set out the parameters for Category IV toxic substances. As pointed out, OSHA intends to initiate with EPA discussions leading to an agreement so that information submitted to EPA under the Toxic Substances Control Act concerning these substances, when and if the substance is introduced into American workplaces, will be reported to OSHA without requiring duplicative reporting on the part of the public. Public comment on this specific aspect of this proposal is invited.

Section 1990.103 permits "any interested person" to notify the Secretary, or designee, in writing, of the existence of information concerning any toxic substance. The Secretary shall publish a notice of receipt of this information in the FEDERAL REGISTER, together with a short statement identifying the contents and source of such information. Where relevant data is presently being generated but which is then unavailable to the Secretary, he may delay the publication of the receipt of the information up to, but no longer than, 180 days. In most cases a comment period of at least thirty (30) days but no longer than sixty (60) days shall be provided. However, where the Secretary finds that extraordinary circumstances warrant less or no time for comment, he may issue an ETS without such an opportunity for any comments. After the comment period, the Secretary of required to classify within thirty (30) days the toxic substance into one of three possible categories (discussed further below) and publish in the FEDERAL REGISTER a notice and an explanation of his decision.

While § 1990.103 enables any interested party to present information to the Secretary for the classification of any toxic substance, as defined, it does not preclude OSHA from devising its own system for the orderly, systematic classification of the large number of potential carcinogens already identified by NIOSH. In fact, OSHA recognizes the backlog of substances that will confront it at the outset of a regulatory program such as proposed. OSHA therefore intends to develop a separate schedule, if such is warranted, even while implementing this proposal as to other toxic substances, to permit the orderly handling of the hundreds of compounds with allegedly some degree of evidence of tumorigenicity or carcinogenicity, as identified by NIOSH. For example, where the evidence is sufficient to classify a toxic substance on the NIOSH list as a Category I toxic substance but where the evidence is not relatively recent, one option available to OSHA in implementing this separate schedule might be to commence the regulatory process by a notice of proposed rulemaking pursuant to § 1990.160 herein and section 6(b) of the Act, rather than by the issuance of an ETS pursuant to § 1990.150 herein and section 6(c) of the Act. Another option would be to decide how many years should be taken to handle the NIOSH list, such as 3 years, and then take the NIOSH identified substances on an alphabetical basis. OSHA solicits public comment as to the best way to imple-

ment these regulations insofar as those substances identified as "suspect carcinogens" by NIOSH are concerned.

Sections 1990.110, 1990.120, and 1990.130 define three categories for the classification of toxic substances, namely: Category I toxic substances, Category II toxic substances and Category III toxic substances. The classification is determined by the kind and degree of evidence indicating that a substance may, or may not, pose a carcinogenic risk to workers and thereafter governs the type of responsive protective action which OSHA will appropriately take. In addition, and notwithstanding the other provisions of these proposed regulations, section 1990.140 provides for Category IV toxic substances, namely, those foreign toxic substances, as defined, for which no standards will be issued during the duration of that classification.

1. *Category I Toxic Substances.* Section 1990.110 establishes a presumption that a substance shall be classified by the Secretary as a "Category I Toxic Substance" if the evidence concerning such substance meets the definition of a potential occupational carcinogen and the evidence was developed: (a) in humans; (b) in two mammalian test species; (c) in a single mammalian species, if those results have been replicated in the same species in another experiment or supported by short-term tests, as defined; or (d) upon the basis of any other scientific evidence that the Secretary finds sufficient. A result is considered to have been replicated if a similar significant increase in tumor incidence is induced in the same or different strain of the particular species so long as the experiments were carried out independently (i.e. at the least, with independent sets of control animals). If the evidence satisfies any of these criteria, the presumption exists that the Secretary shall classify the substance as a "Category I Toxic Substance."

The basis for these criteria initiating a Category I classification are predicated upon the discussions above and here. First, despite the inherent limitations of epidemiological studies in humans, where such studies indicate positive results, even where there is a small cohort of workers, OSHA believes that exposure to such a substance gives rise to great concern. Thus, the proposed set of regulations provides that such evidence in humans at least presumptively initiates a Category I classification, unless the evidence is "only suggestive" in which case the evidence initiates the Category II classification. It is only where the human evidence is "totally inadequate" that OSHA will classify the toxic substance as a Category III toxic substance. OSHA believes that responsible public regulation in matters concerning human health requires no less action or caution.

Second, as pointed out above, OSHA intends to qualitatively treat a toxic substance that produces cancer in at least two species of test animals as posing a potential carcinogenic risk to humans. This is so because positive results in at least two species of test animals generally replicate the results of each test and thus gives rise to a higher degree of confidence in those results than might exist in the case of results arising from a single unreplicated study, so long as the grounds for rebutting the presumption are not found appropriate, as discussed below. The risk of cancer is "sensitive and fright-laden" (*EDF* v. *EPA*, 465 F. 2d 528, 538 (1972)). Although the Delaney Clause is not applicable to the statutory mandate of the Act, it has been stated that it:

> • • • does, however, indicate the magnitude of Congressional concern about the hazards created by carcinogenic chemicals, and places a heavy burden on any administrative officer to explain the basis for his decision to permit the continued use of a chemical known to produce cancer in experimental animals. *EDF* v. *Ruckelshaus*, 439 F. 2d 543 at 596, n. 41.

Third, OSHA recognizes that the results from a single study in a single species can be in error. OSHA therefore believes that before it regulates a toxic substance as a Category I toxic substance, that positive animal test results be replicated either by similar results in another species, as pointed out above, a replicated study in the same animal species or supported by short-term tests, as defined. Insofar as the validity of short-term testing is concerned, at the present time OSHA relies upon the National Cancer Advisory Board of NCI, and the discussion above. It should be noted that reliance upon replicated experiments in a single species of test animals is not new and has been accepted by other Federal agencies. FDA, in banning chloroform, as discussed above, relied almost exclusively on mouse data. And, in his aldrin and dieldrin suspension decision, EPA Administrator Russell E. Train stated:

> Some witnesses also suggested that carcinogens can be species-specific—that is, a chemical substance might affect mice but not any other species, including man. This is theoretically possible. But of the thousands of compounds tested, the record indicates that this effect has been suggested for only one of them, and even this single exception has been seriously challenged. I therefore will rely on the conclusion of such organizations as the International Association for Research on Cancer, which have rejected species-specificity as unsubstantiated.
>
> If carcinogens are not species-specific, it logically follows that the demonstration of carcinogenic effect in more than one species is not absolutely necessary for a finding of carcinogenicity.[4]
>
> Most carcinogens are also not organ-specific. In a survey by Dr. Thomatis of 58 compounds known to produce liver tumors in mice, 40 also induced tumors in a variety of other organs. Furthermore, chemically-induced tumors in one species need not appear in the same organ in another species. Thus, a carcinogen which induces liver tumors in mice might, for example, produce mammary cancers in rats and lung tumors in men.

[4] An HEW Advisory Panel has recommended that a finding of carcinogenicity be made when a substance is "judged positive for tumor induction in *one* or more species • • •." (EPA Ex. 40F, p. 468)

And, in that same proceeding, Dr. Arthur C. Upton, then Dean of the School of Basic Health Sciences at the State University of New York at Stony Brook, New York and now Director of the National Cancer Institute, testified:

> Given this lack of knowledge concerning mechanisms, I believe that a carcinogenic reaction in any species of test animal must be considered sufficient to describe the test compound as a carcinogen and so a threat to human health. I consider that a similar reaction in a second mammalian species is a confirmation of the carcinogenicity of the test agent but it is not necessary before a finding of carcinogenicity and threat to human health can be made; any negative results in a second or even third species of test animal do not in my mind establish that the test agent is not a threat for human beings. Given the variation in human susceptibility to carcinogens, I believe it unreasonable to ignore a finding of carcinogenicity in any mammalian test species when considering possible effects on human health. (*EPA* Ex. S–19 at pp. 4–5)

Likewise, three other emminent scientists testified to the some effect in that same proceeding. Doctor Melvin D. Reuber, then Associate Professor of Pathology at the University of Maryland School of Medicine and formerly a staff pathologist at NCI, testified:

> Sufficient documentation is available on qualitative extrapolation of animal data that one must conclude that a finding of carcinogenicity in one mammalian species should be deemed to have relevance for other mammalian species—including man. (EPA Ex. 42, p. 47)

A similar conclusion was drawn by Dr. Walter E. Heston, then Chief of the Laboratory of Biology at NCI, a position that he had held since 1961. Dr. Heston testified:

> If a chemical causes a neoplastic change in the liver of a mouse or rat, we would expect that through a comparable mechanism it could cause a neoplastic change in the liver of man if given in adequate doses to genetically susceptible individuals. If an agent causes the neoplastic transformation in cells of any organ of the mouse, one would expect that in some human beings, cells either in the same organ or possibly in some other organ that were exposed to the same agent would also become neoplastic. (EPA Ex. 46, p. 9; see also EPA Ex. S–11, p. 7)

Moreover, Dr. Heston further testified:

> Knowing this, and knowing the general biological similarity of mice and other mammalian species, including man, we can reasonably expect that in a population of human beings exposed to Aldrin-Dieldrin, cancer of some kind will occur in some individuals, and these individuals will not have been afflicted in the absence of these compounds • • •. The human population is so much more genetically diverse than any laboratory animals, that if a chemical has been shown to be carcinogenic by a significant induction in *any* laboratory strain of mammal, we can reasonably expect that at least certain human beings would also respond to the chemical by developing some kind of neoplasm. (EPA ex. S–11, 5–7)

And, finally, as unequivocal as the testimony of Dr. Upton was the testimony of Dr. Emmanuel Farber, then Professor of Pathology and Biochemistry and Director of the Fels Research Institute of the

Temple University School of Medicine, Philadelphia, who testified:

> • • • any compound shown clearly to be a carcinogen in any animal species, especially a mammal, must be considered as a possible or even probable carcinogen for man. (EPA Ex. 45, p. 4)

Finally, the proposed set of regulations for any other evidence to initiate a Category I classification, if the Secretary so determines. This basis is meant to include evidence, for example, of those substances that might possess a unique property, e.g., a substance that generates nonstatistically significant but extremely rare or unusual tumors, such as brain tumors, that might not otherwise, standing alone, meet the other criteria for a Category I classification. This might also include evidence from a single, exceptionally well conducted, test in one animal species, as well.

Section 1990.111 sets forth the circumstances under which the Secretary determines that the evidence rebuts the presumption of a Category I classification. This section is one of the key sections of this proposed set of regulations. The Secretary may find that a Category I classification of a substance is not warranted if he scientifically determines on the basis of the evidence: (a) that the alleged carcinogenic effect based on animal data clearly resulted from nonspecific physical, rather than chemical induction; (b) that the route of exposure was grossly inappropriate relative to the potential occupational routes of human exposure; (c) that the animal or human studies submitted for review were only suggestive; (d) that the human or animal studies are totally inadequate to establish any conclusion with respect to the carcinogenicity or noncarcinogenicity of the toxic substances; or (e) that for some other scientific reason, the positive results in experimental mammals are not relevant to man. Any such determination by the Secretary shall be after consultation with the Director of NIOSH and published in the FEDERAL REGISTER. In the event that the Secretary finds that a Category I classification has been rebutted, he shall classify the substance as either a Category II or III toxic substance.

The first two bases for rebutting the presumption of a Category I classification reflect the advice of the Ad Hoc Committee to the Surgeon General in 1970, as cited above. There, the Committee stated:

> 1. a. Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man. Exceptions should be considered only where the carcinogenic effect is clearly shown to result from physical, rather than chemical, induction, or where the route of administration is shown to be grossly inappropriate in terms of conceivable human exposure. (p. 1)

The third basis for rebutting the presumption that a toxic substance should be classified as a Category I toxic substance has been provided because OSHA believes that some suggestive evidence of carcinogenicity, where perhaps not conclusive and therefore not sufficient to support a full blown regulation of the substance as a carcinogen, raises, nevertheless, a yellow flag of caution. OSHA believes in such a case that responsible public policy dictates that some regulation of the toxic substance should occur even if the evidence is "only suggestive" of carcinogenicity. Therefore, provisions such as medical surveillance of employees, exposure monitoring, and the other requirements of the model standard found in section 1990.160 are considered appropriate. However, as pointed out below, OSHA recognizes that in general, the most cost intensive items found in the Category I model standard are the requirements that the permissible exposure limits be set as low as feasible and be achieved by way of equipment or work practice controls. Thus, because of the lower qualitative and quantitative evidence required for a Category II classification, OSHA has not required that permissible exposure limits be reduced to as low as feasible, as in the case of a Category I toxic substance.

The fourth rebuttal criterion is implicit in the Ad Hoc Surgeon General's Committee's Report, namely that if the studies are scientifically totally inadequate, for example in methodology or conduct, then OSHA will not rely upon such studies at all.

Finally, because of possible legal necessity or the needed flexibility in the field of scientific research, the proposed set of regulations provides that OSHA will rebut the presumption of a Category I classification if it can be shown that "for some other" scientific reason, the results in experimental animals "are not scientifically relevant to man." OSHA is reluctant to add this fifth option, for OSHA does not intend to reopen discussion and litigation on the scientific issues foreclosed by these regulations, such as whether a tumorogen should be regulated as a carcinogen. OSHA specifically invites public comment on this issue and its scientific and legal necessity and relevance.

Section 1990.112 sets forth the regulatory consequences of a Category I classification, which include, among other things, the issuance of an emergency temporary standard, in accordance with section 6(c) of the Act, and a proposed permanent standard, in accordance with section 6(b) of the Act. The permissible exposure limits in both model standards must be set as low as feasible. The model permanent standard also provides that when it is determined by the Secretary that there are suitable substitutes for certain uses or classes of uses that are less hazardous to humans, on the basis of the best available evidence, the proposal shall permit no occupational exposure. These requirements concerning the setting of permissible exposure limits, namely, as low as feasible, is one of those requirements that may not be deviated from in the standard setting process in the subsequent rulemakings.

Section 1990.113 provides for a public hearing pursuant to section 6(b) of the Act, if requested or upon the Secretary's own initiative. In addition, § 1990.113 describes the issues to which the scope of such a hearing is limited. They are: (1) whether the Secretary correctly classified the toxic material as a Category I Toxic Substance; (2) whether the Secretary was correct in the determination that the Category I classification should not be rebutted; (3) whether the Secretary correctly determined the lowest feasible occupational exposure, and whether there are suitable substitutes that are less hazardous to humans; (4) whether the toxic substance has unique properties or uses that make any of the specific protective measures of the model standard inappropriate or infeasible; and (5) the environmental impact arising from regulation of the toxic substance.

Section 1990.114 provides that at the conclusion of the rulemaking as to the specific substance, the Secretary has three options. First, if he determines, based on the record, that he was correct in his initial classification of the toxic substance as Category I, he is required to issue a standard that shall follow the content and format of the model standard set forth in § 1990.160. This is the "full-blown" OSHA carcinogen standard. The permissible exposure limits shall, as pointed out, reflect the lowest feasible levels and, where it is determined by the Secretary that there are suitable substitutes that are less hazardous to humans, no occupational exposure shall be permitted. As we point out below in discussing this specific requirement, "no occupational exposure" does not mean a ban of the use of the substance; for example, a substance might be used where it can be used in a truly closed system.

Second, if the Secretary determines, based on the record, that the toxic substance should have been classified as a Category II toxic substance, he is required to issue a standard following the content and format of the model permanent standard set forth in § 1990.170.

Finally, if the Secretary determines, based on the record, that the toxic substance should be classified as a Category III toxic substance, he is required to follow the procedures provided by section 1990.131, *et. seq.* These procedures however, as pointed out, do not require regulatory action.

2. *Category II Toxic Substances.* Section 1990.120 establishes that certain evidence mandates a Category II classification while other evidence only triggers a presumption that a substance shall be classified as a "Category II Toxic Substance". If the substance meets the definition of a potential occupational carcinogen (as was the case with a Category I toxic substance) but the evidence was scientifically found to be "only suggestive" by the Secretary in determining not to classify the substances as Category I, the Secretary is required to classify the toxic substance as a Category II toxic substance. This classification is not discretionary on the part of the Secretary and may not be deviated from. This is so because any evidence in humans or in

more than one mammalian test animal species or in one such species that is replicated, as defined, that is not totally inadequate obviously forms the basis for some degree of concern. In addition, if the evidence meets the definition of a "potential occupational carcinogen" in an unreplicated experiment in only one mammalian species or the Secretary finds that any other evidence is sufficiently convincing that the toxic substance should be classified, as posing some carcinogenic risk, a presumption exists that the toxic substance shall be classified as a "Category II Toxic Substance".

Section 1990.121 sets forth the circumstances under which the Secretary may rebut the presumption of a Category II classification. First, it should be pointed out, as it was above, that if the evidence would have supported a Category I classification but for the finding that the evidence was "only suggestive", the classification of Category II is not presumptive but mandatory. Thus the presumptive nature of the Category II classification exists only for evidence based on unreplicated animal data in one mammalian animal species or other evidence that the Secretary finds sufficient. The grounds to rebut that limited presumption are exactly the same as those used to rebut the Category I presumption, with the exception of the finding that the evidence is "only suggestive". Because OSHA believes that this evidence will generally consist of one study in a single mammalian species, OSHA believes that if the evidence is "less than suggestive" but not totally inadequate, regulatory activity may be unjustified. Thus, the proposal provides that the Secretary may rebut the presumption that a toxic material be classified as a Category II toxic substance where the evidence in the unreplicated experiment in a single mammalian test species is less than suggestive, as defined (but by definition not totally inadequate). As with the rebuttal of a presumptive classification of a Category I toxic substances, any such rebuttal by the Secretary shall be after consultation with the Director of NIOSH, and published in the FEDERAL REGISTER. In the event that the Secretary finds that a presumptive Category II classification has been rebutted, he shall classify the material as a Category III toxic substance.

Section 1990.122 sets forth the regulatory consequences of a Category II classification, which includes, among other things, the issuance of a proposed permanent standard in accordance with section 6(b) of the Act. As will be pointed out, the permissible exposure limits found in the proposed model standard will not be changed from those If no OSHA standard exists or the presin a present OSHA standard if one exists. ent OSHA standard is inadequate, based on evidence of acute or chronic effects other then carcinogenicity, the exposure limits shall be set at levels found appropriate by the Secretary to protect against such acute or chronic effects. OSHA is concerned that this requirement may result in rulemakings under this subpart for such a Category II toxic substance that will be consumed by issues concerning toxic effects other than carcinogenicity. One obvious alternative to the proposal would be to keep the present OSHA standard or, where there is none, not to attempt to set permissible exposure limits in that rulemaking. The limits might be set in a subsequent rulemaking devoted entirely to that issue. This alternative, of course, could provide that in cases, where good evidence is in hand as to other toxic effects, the Secretary would set a level or lower the present, OSHA standard, where appropriate. Because one of the essential reasons for this proposal is to speed up regulatory activity as to occupational exposure to potential carcinogens, OSHA seeks and invites the widest public comments and views as to how to handle the problems posed by an inadequate, or nonexistant OSHA standard for Category II toxic substances. It should be pointed out, as we have above, that the Category II classification exists for those substances for which the evidence raises concern about possible carcinogenic effects of exposure but not as high degree of confidence. Thus, OSHA believes that some regulation of such a substance should occur, where perhaps none occurred in the past. However, OSHA believes that, in general, the most cost intensive items found in the "full-blown" carcinogen standard are the requirements that the mandated permissible limits be set as low as feasible and be achieved by way of equipment or work practice control. Thus, with respect to the potential cancer hazard of a Category II toxic substance OSHA does not believe it appropriate to impose the requirement that permissible exposure limits be reduced to the lowest feasible levels.

Section 1990.122 also gives notice that if, pursuant to the rulemaking, the Secretary determines that the substance should have been classified as a Category I toxic substance, the final standard will be that required for a Category I toxic substance, as required by § 1990.160. The regulation also specifically requires that the Secretary give explicit notice of this possibility in the notice of proposed rulemaking for a Category II substance. This provision exists because OSHA believes that it would serve no purpose to have multiple rulemakings on the same substance, particularly where adequate notice of the possibility of such events is given in advance to the concerned public.

Section 1990.123 describes the issues to which the scope of such a hearing is limited. Those issues are exactly the same as those to which hearings and comments are limited as to Category I toxic substances.

Finally, § 1990.124, as did § 1990.114, provides that, at the conclusion of the public rulemaking, the Secretary has three options. First, if he determines that he was correct in his initial classification of the toxic substance as a Category II toxic substance, he is required to issue a standard that shall follow the content and format of the model standard set forth in § 1990.170.

Second, if the Secretary determines that the toxic substance should have been classified as a Category I toxic substance, he is required to issue a standard that shall follow the content and format of the model standard set forth in § 1990.160.

Third, if the Secretary determines that the toxic substance should have been classified as a Category III toxic substance, he is required to follow the procedures provided by § 1990.131, *et seq.*

3. *Category III Toxic Substances.* Section 1990.130 provides that any toxic substance, as defined, not classified by the Secretary as a Category I or II toxic substance shall be classified as a Category III toxic substance. Naturally, this does not include Category IV toxic substances. Basically the Category III classification includes substances for which there is meager or no valid scientific evidence indicating that the substance has a carcinogenic potential to humans. Moreover, it may also include substances for which there is some evidence of a lack of carcinogenic activity. This is not to say however that OSHA has determined by such classification that the toxic substance does not pose a carcinogenic risk—it is merely to say that on the basis of the present evidence, one cannot say that it does. No regulation of this category of toxic substance is provided, insofar as carcinogenicity is concerned. Regulation will occur through OSHA's present standard setting activity or in the future concerning other acute or chronic effects of exposure.

Section 1990.131 provides that when the Secretary determines that a toxic substance should be classified as a Category III toxic substance, he will publish his determination in the FEDERAL REGISTER and add that substance to the list provided for by § 1990.133, in order to approximately inform the public as to the status of any toxic substance for which there is no Category I or Category II standard. The Secretary is also required to transmit his findings to EPA, NIOSH, NCI and CPSC with a request that each agency determine if there is additional information, unavailable to, or unreviewed by, the Secretary that might be relevant to the classification of that toxic substance.

4. *Category IV Toxic Substances.* OSHA does not believe that prudent government regulation should control substances that are not found in American workplace for several reasons. First, it would be a waste of precious manpower that is needed to regulate substances already found in the workplace. Second, it would be difficult if not impossible to foresee the possible problems concomitant with regulation of substance not yet found in the workplace. For example, uses for a substance might not now exist. When they do, what substitutes for that substance that might exist could not be known with any degree of certainty. And finally, to conduct such a rulemaking would perhaps deprive the public—and thus OSHA—of any meaningful input into such process because of the probable lack of any present in-

terest in participating in such a process for a substance that nobody uses.

Thus OSHA intends to list such substances in section 1990.141. The regulations provide, however, that the Secretary will first publish a notice of intent to list those toxic substances as Category IV toxic substances which he believes are not found in American workplaces, in order to provide an opportunity for public comment. Thereafter, the Secretary will publish and update a list of these substances in the FEDERAL REGISTER and the Code of Federal Regulations. OSHA intends to add or delete from that list but without the formality of rulemaking, *per se*. In addition, OSHA intends to develop a procedure with EPA to coordinate this part of the proposal with EPA's implementation of the Toxic Substances Control Act.

B. THE BASIS AND RATIONALE FOR THE EMERGENCY TEMPORARY STANDARD FOR A CATEGORY I TOXIC SUBSTANCE (1990.150)

The Secretary believes, upon the basis of the preceding discussion of cancer, that when evidence exists that meets the definition of a potential occupational carcinogen and the criteria found in § 1990.110, (a) continued exposure constitutes "a grave danger" within the meaning of section 6(c)(1)(A) of the Act and (b) that an emergency temporary standard as proposed in § 1990.150 is necessary and proper to protect employees from such danger. The proposition that cancer, and substance that cause cancer, pose a grave danger to man does not need lengthy discussion. As pointed out, the nature of a cancer hazard differs from other types of toxicity. Employees exposed to carcinogens risk incurable, irreversible and, in most cases, fatal consequences. These consequences may be irreversibly set in time. No symptomatic evidence of the development of he cancer may be apparent to the employee during a long latency period. A singlee xposure episode may be sufficient to cause cancer. These factors, which establish the grave danger posed by exposure to carcinogens, also lead inexorably to the conclusion that it is necessary to provide protection for employees as soon as possible through the issuance of an emergency temporary standard, within the meaning of section 6(c)(1)(B) of the Act.

Further, another basis for immediate action arises from the nature of the disease itself. If cancer were a reversible, generally curable disease, there might be some justification for pursuing a standard by some other procedure than an ETS. For example, a worker contracting the disease during the time required to complete full rulemaking proceedings might possibly be cured at some subsequent time. However, cancer is not generally reversible. The Court of Appeals in *Florida Peach Growers* v. *Brennan* 489 F. 2d 120 (5th Cir. 1974) emphasized the importance of irreversibility in its interpretation of some of the criteria that might be necessary to sustain an emergency temporary standard. The Court stated:

> We reject any suggestion that deaths must occur before health and safety standards may be adopted. Nevertheless, the danger of incurable, permanent, or fatal consequences to workers as opposed to readily curable and fleeting effects on their health, become important in the consideration of the necessity for emergency measures to meet a grave danger. 489 F. 2d at 132.

The model emergency temporary standard contains those provisions deemed necessary and possible to immediately provide employee protection pending completion of the 6(b) permanent rulemaking proceedings to commence shortly thereafter. OSHA firmly believes that when a toxic substance meets all of the criteria and definitions herein, it would be unconscionable not to require those actions that can be done immediately to reduce human exposure. Simply put, the model emergency temporary standard, in general, would require the employer to identify exposed employees, measure their exposures, inform them of the hazards associated with exposure to the toxic substance, provide medical examinations, and reduce their exposures to the lowest level possible that, in OSHA's judgment, can be complied with immediately through any practicable combination of engineering, work practice, and appropriate personal protective equipment control. It would not require that the reduction of employee exposures to the permissible exposure limits be achieved solely by way of equipment or work practice controls, as described more fully below.

Additionally, the ETS would require employers to notify OSHA of the location of workplaces in which employees are exposed to the Category I toxic substance and to describe the conditions of use and exposure and protective measures in effect. Such information will facilitate OSHA's decisions in the subsequent rulemaking proceedings by providing information concerning the extent of use, number of exposed employees, other facts relevant to determination of feasible exposure limits and the appropriateness of specific regulatory provisions.

C. THE BASIS AND RATIONALE FOR THE REQUIREMENTS OF THE THREE MODEL PROPOSED STANDARDS: 1. THE CATEGORY I TOXIC SUBSTANCE ETS (1990.150); 2. THE CATEGORY I TOXIC SUBSTANCE PERMANENT STANDARD (1990.160); AND 3. THE CATEGORY II TOXIC SUBSTANCE PERMANENT STANDARD (1990.170)

The following discussion summarizes the significant provisions of the three model standards and the rationale and policy considerations underlying those provisions. As pointed out, these three model standards are intended to be proposed and promulgated in their entirety, in form and content, in each of the substance-by-substance rulemakings, except where deviations, additions or changes are shown to be appropriate. However, certain provisions of the model standards, which represent basic policy decisions of OSHA, such as the requirement that the lowest feasible levels of exposure to be achieved for Category I toxic substances, will not be permitted to be changed in the subsequent substance-by-substance rulemakings. Other requirements, such as the content of medical tests and procedures, may properly vary according to the unique properties or uses of the substance to be regulated and the appropriateness of such requirements will be obviously issues in the subsequent 6(b) rulemaking. Therefore, §§ 1990.113 and 1990.123 permit the rulemaking proceedings on specific substances to consider whether the unique properties or uses of the substance make any of the specific protective measures of the model standards inappropriate or infeasible. For example, in the recent proposal to regulate occupational exposure to benzene (42 FR 27452), no provision was made for change rooms or showers. This omission from usual OSHA requirements for occupational exposure to a carcinogen occurred because the high volatility of benzene made such requirements unnecessary as to the regulation of that toxic substance.

In format, OSHA has identically lettered those provisions appearing in the model ETS and the model permanent standards for Category I and Category II toxic substances, which cover the same subject headings, for the convenience of the public. For example, paragraph (n) in all three model standards will always contain the requirements for medical surveillance, whether it be the model ETS or the model standards for Category I or Category II toxic substances. Where inappropriate provisions are deleted, for example the regulated area requirement is omitted from the ETS, the lettered paragraph will nonetheless appear with the notation "deleted" to maintain consistency throughout the three model standards.

For the convenience of the public, OSHA attempts here to graphically illustrate, in general, as Table I, the requirements of, and differences in, the three model standards. This table does not, however replace the discussion of the individual requirements, as Table I can only generalize. In addition, attached to this proposed set of regulations, as Appendix A, is a three column display of the three model proposed standards side by side. OSHA believes that Table I and Appendix A will greatly facilitate public understanding and response to this rulemaking.

TABLE I

Description of the 3 model standards, as proposed	Category I: Toxic substances emergency temporary standard	Category I: Toxic substances standard	Category II: Toxic substances standard
1. Sec. (a): Scope and application.	As provided	As provided	As provided.
2. Sec. (b): Definitions	do	do	Do.
3. Sec. (c): Permissible exposure limits.	Levels are to reflect the lowest levels feasible that can be achieved within the shortest possible time.	Levels are to reflect the lowest levels feasible or, in certain cases, the levels shall permit no occupational exposures.	Levels are to retain the present OSHA standard (29 CFR 1910.1000) or if none or inadequate, the appropriate levels based on acute or chronic non-carcinogenic effects.
4. Sec. (d): Notification of use and emergencies.	Provides for notification of use.	Provides for notification of use and emergencies.	Provides for notification of use and emergencies.
5. Sec. (e): Exposure monitoring and measurements.	Monthly if above limits set by sec. (c); quarterly otherwise.	Monthly if above limits set by sec. (c); quarterly otherwise.	Monthly if above limits set by sec. (c); quarterly otherwise.
6. Sec. (f): Regulated areas	Omits this requirement	Required	Omits this requirement.
7. Sec. (g): Methods of compliance.	Any combination of equipment controls, and personal protective equipment.	By way of engineering and work practice controls only, except in certain circumstances.	By way of engineering and work practice controls only, except in certain circumstances.
8. Sec. (h): Respiratory protection.	Required	Required	Required.
9. Sec. (i): Emergency situations.	Omits this requirement	do	Do.
10. Sec. (j): Protective clothing and equipment.	Some of the requirements	All of the requirements	All of the requirements.
11. Sec. (k): Housekeeping	Required	Required	Required.
12. Sec. (l): Waste disposal	do	do	Do.
13. Sec. (m): Hygiene facilities.	Some of the requirements	All of the requirements	Some of the requirements.
14. Sec. (n): Medical surveillance.	Required	Required	Required.
15. Sec. (o): Employee training and education.	do	do	Do.
16. Sec. (p): Precautionary signs and labels.	do	do	Do.
17. Sec. (q): Recordkeeping	do	do	Do.
18. Sec. (r): Observation of monitoring.	do	do	Do.
19. Sec. (s): Effective dates	Immediately	As determined in the proposed or final standard.	As determined in the proposed or final standard.
20. Sec. (t): Appendices	Will be provided	Will be provided	Will be provided.

1. *Paragraph (a): Scope and Application.* The three proposed model standards would apply to all workplaces in all industries, including the general, construction, maritime, and agriculture industries, wherever occupational exposure to the toxic substance, as defined, occurs. The three model standards also provide for instances where the standard will be determined by OSHA not to apply, if applicable. The wordings of the three model standards, as proposed, are identical in this regard, although in their application they will obviously be different. See for example, the differences between the final Coke Oven Emissions Standard (29 CFR 1910.1029), the final Vinyl Chloride standard (29 CFR 1910.-1017) and the recent Benzene proposal (42 FR 47452).

2. *Paragraph (b): Definitions.* The three proposed model standards contain definitions in order to establish a consistent working vocabulary. OSHA considers these definitions to be minimal insofar as the model standards are concerned. There are some differences, however, even as proposed, in the three model standards because of deleted or additional requirements found in the body of each standard, as discussed. However, there are no differences in the definitions common to the standards.

3. *Paragraph (c): Permissible Exposure Limits.* The proposed ETS and the model permanent standard for a Category I toxic substance would require that employee exposure to a Category I toxic substance be reduced to the lowest levels feasible. In practice, it may be that the permissible exposure limits for the ETS might be higher or lower than those proposed or promulgated in the permanent model standard because of the opportunity for a better assessment of feasibility during the comment period and possible hearing. Additionally, where, on the basis of facts set forth in the proposal or on the record of the public rulemaking, suitable substitutes in certain applications or uses are found to exist which are less hazardous to workers, the Secretary shall prohibit, in the permanent standard, occupational exposure for such specific applications or uses. This prohibition against occupational exposure is not *per se* a ban upon the use of the toxic substance, unless otherwise noted. Any such use of the toxic substance might, for example, be safely contained in a system that would not create any occupational exposure even when the toxic substance were still being used.

The policy decision to reduce exposures to as low as feasible, or to prohibit occupational exposure where suitable substitutes exist, is not made without sound support. As has been discussed above, a no-effect or threshold level may theoretically exist for any specific carcinogen. As yet, however, there is no satisfactory scientific basis for determining such levels for any given population. Thus, as has been proposed, any human exposure to a carcinogen, even at levels below those which induced positive effects in man or in test animals, would be considered by OSHA to present a potential cancer risk as a policy matter. We do not know whether "safe" or "no-effect" levels exist for a carcinogen and, if so what they may be. Therefore, attempts to set finite exposure limits are not directed at determining "safe" levels of exposure but rather are attempts to determine the lowest feasible levels.

OSHA intends to permit no deviation from the general policy, that the employee exposure limits in the ETS and permanent Category I standard shall always be "the lowest feasible level". OSHA does not believe that it should deviate, in the substance by substance rulemakings themselves, from the position proposed to be established in this rulemaking, namely, that when dealing with human carcinogens it is appropriate to set a level which assures the lowest feasible risk to workers. If and when substantial evidence is available to show that "safe" or "no-effect" levels can be predicted for exposure of human beings to carcinogens, OSHA will act to amend this basic policy decision reflected in this set of regulations proposed today.

The two model permanent standards for Category I and Category II toxic substances provide for permissible exposure limits for inhalation over a time weighted average for an 8 hour day and a ceiling level for any prescribed appropriate interval during that day. They also provide that no employee shall be exposed to eye contact or repeated skin contact. The only difference is that insofar as the model permanent standard for a Category I toxic substance is concerned, the ceiling level shall not be over five (5) times the time weighted average for the inhalation permissible exposure limit. This is provided because statistically, an employer can not generally assure that his employees' exposures are below the time weighted average limit unless the ceiling exposures are less than 5 times that limit.

Finally, the proposed permanent standard for a Category II toxic substance differs markedly from the requirements for Category I toxic substances concerning the permissible exposure limits. This is so because of the lower quantity or quality of the evidence being relied upon. Thus, the model standard for a Category II toxic substance: (a) retains the present OSHA standard found in 29 CFR 1910.1000 or (b) where none exists, sets an appropriate level based upon acute or chronic effects of exposure other than carcinogenicity to the toxic substance, or (c) where acute or chronic effects of exposure other than carcinogenicity indicate that the present OSHA standard is inadequate, lowers the exposure level from the present OSHA standard to the level found appropriate by the Secretary, in the record, to protect against such effects. As has been pointed out above, OSHA is concerned about this specific provision of the Category II model permanent standard and invites the widest public comment as to whether the lowering or setting of permissible exposure levels for such a substance should await a subsequent rulemaking, except where the Secretary determines that he has sufficient evidence in hand at the time.

4. *Paragraph (d): Notification of Use and Emergencies.* The three model standards all provide that within a certain time after the effective date of each

standard, the employer shall notify the applicable OSHA area office as to the address and location of each workplace in which employee exposure to the toxic substance occurs, a brief description of the work operations and the number of employees that may be exposed.

In addition, the Category I and II proposed permanent standards provide that the employer must also notify the OSHA area office when emergencies, as defined, have occurred. If the OSHA area office requests additional information relevant to the emergency, the employer will be required to furnish such information, together with a description of measures taken to prevent future emergencies of a similar nature. The model ETS does not include this requirement because it does not require written plans for emergency situations, for the reasons set forth in paragraph 9 below. Moreover, because previous employee exposures may be at levels much higher than the ceiling limits and compliance with the lower levels set by the ETS is most likely to be achieved by respirators, OSHA deems such requirement to be unnecessary or even infeasible for the ETS. Finally, in light of the other requirements mandated of employers by the ETS, OSHA believes that such a further requirement might be overburdensome in the case of most employers because of the short effective period of the ETS (6 months).

These reports of use, and in the case of the two model permanent standards, the report of emergencies, are considered necessary and proper in order to aid enforcement activities. In addition, such information is helpful, in the case of the rulemaking concerning the permanent standard for Category I toxic substances, in determining what level of exposure can feasibly be attained by way of engineering and work practice controls. Finally, such reports are necessary in order to monitor the effectiveness of standards in protecting employees against occupational cancer and in order to obtain information, on a continuing basis, concerning the hazards found in the use of these toxic substances.

OSHA recognizes that the reporting of use may be a requirement of the United States Environmental Protection Agency pursuant to the Toxic Substances Control Act of 1976. OSHA does not desire duplication of reporting to more than one Federal agency and therefore directs the attention of the public to this issue and requests comments on ways to achieve notification of use without duplicating reports concerning the use of any given toxic substance. It is OSHA's intention to enter into an agreement with EPA reducing, to the maximum extent possible, any such duplication in reporting requirements.

5. *Paragraph (e): Exposure Monitoring and Measurement.* The three model standards require each employer who has a place of employment where the toxic substance is present to monitor employees to measure their exposure to the toxic substance over an eight (8) hour period, without regard to the use of respiratory protection. Section 6(b)(7) of the Act (29 U.S.C. 655) mandates that any standard promulgated under the Act shall, where appropriate, provide for monitoring or measuring of employee exposure and in such manner as may be necessary for the protection of employees. In addition, section 8(c)(3) of the Act (29 U.S.C. 657) requires employers to promptly notify any employee who has been or is being exposed to toxic substances or harmful physical agents at levels which exceed those prescribed by an applicable occupational safety and health standard and to inform such employee of the corrective action being taken to reduce such exposures. Exposure monitoring is necessary, therefore, in order to determine whether employees are being exposed to the toxic substance at levels exceeding those prescribed by the standard and therefore should be notified as required by the Act.

In addition to the statutory requirements, there are various other reasons which make it appropriate for employers to measure employee exposure to the toxic substance.

First, employers would have a legal obligation imposed by the individual standard to assure that their employees are not exposed above the permissible exposure limits. Exposure monitoring informs the employer whether that obligation is being met.

Second, if the employer determines that employee exposures exceed the permissible exposure limits, then there would be an obligation in the case of a permanent standard for Category I or II toxic substances to institute engineering and work practice controls in order to reduce exposures to the permissible exposure levels. Hence, exposure monitoring aids the evaluation of the effectiveness of the installation of engineering and work practice controls and informs the employer whether additional controls need be instituted. For the same reasons, the ETS requires the use of respiratory protection whenever the permissible exposure limits are exceeded.

Third, if the permissible exposure limits are exceeded, either before all feasible engineering and work practice controls have been instituted, or after, then there is an obligation to use respiratory protection to reduce exposures. The selection of a particular respirator depends largely on the level at which employees are being exposed. Therefore, exposure monitoring is necessary in order to determine whether respiratory protection is required at all, and if so, which respirator is to be selected.

Finally, the results of exposure monitoring are a necessary part of the information which is required to be supplied to the physician to enable him to perform his stated functions under the standard.

The three model standards require that the measurements be made by monitoring which is representative of each employee's exposure to the toxic substance over an eight-hour (8) period without regard to the use of respiratory protection. In order to use the results of exposure monitoring to evaluate the effectiveness of the required engineering and work practice controls, to determine whether additional controls must be instituted, and to ascertain which, if any, respirator must be used, it is necessary to know employee exposure levels without regard to the use of respiratory protection. Exposure measurements of each individual employee would, of course, be the best indication of that employee's exposure. However, OSHA believes that this may be too burdensome and monitoring which is truly representative of an employee's exposure would provide the necessary information with, in many instances, fewer samples. It should be noted that individual exposure measurements would certainly be considered to be representative and are not precluded by this requirement.

All three model standards require that whenever there has been a production, process, control or personnel change which may result in new or additional exposures to the toxic substance or whenever the employer has any other reason to suspect an increase in employee exposure, the employer shall repeat the required monitoring and measurements for those employees affected by such change or increase. This is necessary so that the employer may take the appropriate actions required, such as providing the appropriate respirator protection or instituting engineering controls.

The three model standards require an employer to notify each employee in writing of that employee's representative exposure measurement within five working days after receipt of the results of any required measurement. Section 8(c)(3) of the Act (49 U.S.C. 667) requires employers to promptly notify an employee who is exposed in excess of the permissible exposure limit. The standard extends that right to employees exposed at or below the permissible exposure limits and establishes the time period involved. OSHA believes that informing employees of their exposure measurement, at or below the permissible exposure limits, contributes to their understanding of their work and its attendant hazards, particularly where no level of exposure is "safe" and the level that is set solely a feasibility level. The success of a control strategy that so intimately involves worker cooperation is highly dependent on such understanding. A period of five (5) working days is believed to be a reasonable time in which to notify the employees. The five day limit fulfills the statutory requirement of promptness, yet accommodates the need to allow time for the written notification to be completed.

Section 8(c)(3) of the Act (29 U.S.C. 657) also provides that whenever measurement results indicate that an employee is exposed in excess of the permissible exposure limits, the employer must also notify the employee of the corrective action being taken to reduce exposure to or below the permissible exposure limits. The three model standards all incorporate this statutory obligation.

The employer is also required to use a method of monitoring and measurement with an accuracy (at a confidence level of 95%) of not more than plus or minus an appropriate level to be determined in each specific rulemaking pursuant to this subpart.

6. *Paragraph (f): Regulated Areas.* The model permanent standard for a Category I toxic substance provides that when employee exposure is in excess of the permissible exposure limits, without regard to respiratory protection, the employer must establish a regulated area and limit access to those areas to authorized persons. The purpose of these requirements is to limit the risk of exposure to as few employees as possible. OSHA believes these requirements will allow operation to continue without undue interference, considering the dangerous hazard to which the workers are exposed.

The model ETS does not include a requirement for the designation of regulated areas. As has been explained, the ETS requirements are those that OSHA has determined and believes can generally be instituted immediately or fairly quickly. Yet, before a regulated area is required, employers would be required to monitor to determine which, if any, employees are exposed to the toxic substance over the permissible exposure limits. OSHA believes that with the present requirements of the model ETS, it would not be feasible in many cases to add this additional requirement to the model ETS.

The model permanent standard for a Category II toxic substance also does not include the requirement for regulated areas. OSHA believes, as has been pointed out, that Category II substances are those substances with substantially less quantitative and qualitative proof of carcinogencity than the Category I toxic substances. In other words, these substances probably have not been regulated in the past by any federal agency insofar as carcinogenicity is concerned. Thus, OSHA believes that requiring regulated areas in the model proposed permanent standard for Category II toxic substances would be too burdensome a requirement based on the quality or quantity of evidence required to trigger a Category II classification.

7. *Paragraph (g): Methods of Compliance.* (a) *The model permanent standards.* The model permanent standards simply restate OSHA's current policy that feasible engineering and work practice controls must be used as the primary methods to reduce employee exposure to or below the permissible exposure limits. They would require the employer to immediately institute feasible engineering and work practice controls to reduce employee exposures to or below the permissible limits, except in situations where the employer proves that such controls are infeasible. Further, in situations where feasible engineering and work practice controls are insufficient to reduce exposure to the permissible limits, they must nonetheless be used to reduce exposures to the lowest achievable level, and then be supplemented by the use of respiratory protection. In addition, a program must be established and implemented to reduce exposures to within the permissible exposure limits or to the greatest extent feasible, solely by means of engineering and work practice controls. Written plans for this program must be developed and be furnished upon request for examination and copying to representatives of the Assistant Secretary and the Director. These plans must be reviewed and updated periodically to reflect the current status of exposure control.

As has been pointed out time and time again in OSHA rulemaking proceedings, respirators are the least satisfactory means of control because of difficulties inherent in their design and use. Respirators are capable of providing good protection only if they are properly selected for the types and concentrations of airborne contaminants present, properly fitted and refitted to the employee, worn by the employee, and replaced when they have ceased to provide protection. While it is theoretically possible for all of these conditions to be met, it is more often the case that they are not. Consequently, the protection of employees by respirators is not always effective and is therefore permitted only in certain specified circumstances. For example, proper facial fit is essential, but due to variations in individual facial dimensions, and the limited range of facepiece configurations, such fit is difficult to achieve. Often the work involved is strenuous and the increased breathing resistance of the respirator reduces their acceptability to employees. Safety problems presented by respirators must also be considered. Respirators limit vision. Speech is also limited. Voice transmission through a respirator can be difficult, annoying and fatiguing. Movement of the jaw in speaking also causes leakage. Communication may make the difference between a safe, efficient operation, on the one hand, and confusion and panic, especially in difficult and dangerous jobs, on the other hand. Also skin irritation can result from wearing a respirator in hot, humid conditions and such irritation can cause considerable distress and disrupt work schedules. The extent of this problem is even greater where the toxic substance is a skin irritant and becomes trapped between the respirator facepiece and the skin.

It is clear therefore that respirators cannot be considered as the primary means of employee health protection. Nevertheless, they do provide some protection and OSHA has concluded therefore that under certain circumstances, the employees must use the respirators provided.

(b) *The Model ETS.* OSHA has indicated herein that the provisions of the model ETS are intended to require only those things which are possible to achieve immediately or within a very short period of time. While the model ETS therefore states that OSHA prefers the reduction of employee exposure by way of engineering and work practice controls, it also states that OSHA recognizes, as a very practical matter, that in many instances, the immediate reduction of exposure will be primarily through the use of respiratory protection, with all of the inadequacies stated above, and the institution of good housekeeping practices such as the prohibitions against the blowing of dust containing the toxic substance or the permitting of open containers and vessels of liquids containing the toxic substances. The methods of compliance, therefore, are a major difference between the model ETS and the model 6(b) proposed and final standards. One other major and distinctive feature of the model ETS is the requirement that during the effective period of the ETS (6 months), the affected employers must look down the road to the model permanent standard for the Category I toxic substance and start planning how to reduce exposures to the lowest feasible levels solely by way of engineering and work practice controls. Thus, OSHA anticipates that by such requirements, delayed effective dates of the permanent standard can be limited or perhaps avoided altogether, hastening the reduction of employee exposure to the toxic substance. Because of the general irreversibility of cancer as pointed out above, OSHA considers the early reduction of employee exposures the most significant provision in decreasing the gravity of the risk of contracting cancer.

8. *Paragraph (h): Respiratory Protection.* The model ETS provides that, whenever the permissible exposure limits are exceeded, the employer shall assure that the employees use respirators. The two model proposed and final standards, however, require that respirators be used to achieve compliance with the permissible exposure limits only during the time period necessary to install or implement feasible engineering and work practice controls, in work operations in which such controls are not technically feasible or are not yet sufficient to reduce exposure to the permissible limit, or in emergencies.

The three model standards require that the employee be properly trained to wear the respirator, to know why the respirator is needed and to understand the limitations of the respirator. An unstanding of the hazards involved is necessary to enable the employee to take steps for his or her own protection. The respiratory protection program implemented by the employer must conform to the program set forth in 29 CFR 1910.134. This section contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

The three proposed model standards also contain a respirator selection table (Table I) so the employer will be informed of and provide the type of respirator which affords the proper degree of protection based on the airborne concentrations of the toxic substance.

To prevent skin irritation and to minimize the discomfort of respirator use, the three model standards require that

employees must be allowed to periodically wash their faces and respirator facepieces in order to remove any accumulation of the toxic substance or to reduce the chance of irritation from the wearing of the facepiece itself, such as a heat rash.

9. *Paragraph (i): Emergency Situations.* The two model permanent standards provide that written plans for emergency situations be developed. They further require that some type of alarm or warning system be devised to adequately alert employees of the emergency. Finally, the two model standards provide for evacuation of all employees from the area except those engaged in correcting the emergency.

The model ETS does not provide such a requirement. As has been pointed out under methods of compliance, OSHA recognizes that respirators may be the primary method used to reduce employee exposure in the short term under the ETS. Thus, the requirements concerning emergencies provided for by the two model proposed and final standards would not appear to be necessary or in some cases attainable for the ETS.

10. *Paragraph (j): Protective Clothing and Equipment.* The three model standards require the employer to provide and assure that employees, who are subject to skin or any eye contact, use protective clothing or equipment such as goggles in order to minimize these hazards.

Basically, the requirements of the three model standards are the same. The three model standards also require that the employer clean, launder, or dispose of the required protective clothing to eliminate any potential exposure that might result were the clothing to be laundered by the employee at home or in a commercial laundry.

The three model standards also require that protective clothing be provided in a clean and dry condition at appropriate times. Since repeated skin contact with many toxic substances, as proposed to be regulated herein, creates a potential for skin cancer, OSHA believes that the regular cleaning of contaminated work clothing plays an important role in the prevention of this hazard. More important, this requirement prevents increased exposure to airborne concentrations of the toxic substance released from the contaminated clothing. The three model standards also require that protective clothing and equipment be maintained and replaced as needed in order to ensure effectiveness.

The two model permanent standards provide that the employer assure that all protective clothing is removed at the end of each work shift, only in change rooms, and that the clothing that is to be laundered, cleaned, or disposed of be placed in a closable container in the change room. The purpose in requiring such a container is to prevent the contaminants on the clothing from coming into contact with an individual handling the container or being released in the change room. Since the container is to be located in the change room, it is appropriate to limit the removal of contaminated clothing to that area.

Finally the three model standards require employers to inform those who handle the contaminated articles of the potentially harmful effects of exposure to the toxic substance. This provision is designed to make clear the need to use proper care in handling of the contaminated articles.

11. *Paragraph (k): Housekeeping.* Removal and prevention of accumulations of the toxic substance dust and liquid deposits on all surfaces in the workplace are important aspects in minimizing employee exposure, particularly in the case of a Category II toxic substance where there may not be a mandatory reduction in the present permissible exposure limits, *per se*. To assure that the toxic substance is not reintroduced into the workplace air, all three model standards prohibit dry sweeping or the use of compressed air for cleaning of floors and other surfaces where the toxic substance dust or liquid deposits are found.

As important, all three model standards require that when the toxic substance is present in a liquid form, or as a resultant vapor, that all containers or vessels shall be enclosed to the maximum extent feasible and tightly covered when not in use.

12. *Paragraph (l): Waste Disposal.* For disposal of waste, scrap, equipment or debris containing the toxic substance, the three model standards require that such substance be collected and disposed in sealed bags or other closed containers which will prevent dispersion of the toxic substance outside of the container.

13. *Paragraph (m): Hygiene Facilities and Practices.* As to the three model standards, there are, generally, the same provisions for hygiene facilities and practices as are provided by present OSHA standards, as mandated by 29 CFR 1910.141.

The two model permanent standards also add other requirements. For example, the model proposed and final standard for a Category I toxic substance also requires that positive pressured, filtered air lunchrooms be provided and readily accessible for employees whenever food or beverages are consumed in the workplace. These lunchrooms must be provided and readily accessible to encourage employees to make use of them. Positive pressure filtered air is required to create a lunchroom with a relatively emission free air supply and to minimize the amount of air from outside the lunchroom blowing inside whenever the door is opened. The air supply is also required to be temperature controlled so that the lunchroom does not become unbearably hot in the summer or cold in the winter, making employees reluctant to use it. In addition, a lunchroom with a temperature controlled air supply will encourage employees not to leave the door open in order to lower the temperature in hot weather, thus minimizing the opportunities for air contaminated with the toxic substance to blow into the lunchroom.

Second, the model permanent standards for Category I and Caegory II toxic substances require the use of hygiene practices and facilities which are intended to remove the toxic substance collected on employees. The standards do this by requiring that the employer assure that employees wash their hands and faces prior to eating. Since washing is required, the model standards also repeat the existing obligation to provide washing facilities and lavatories in accordance with 29 CFR 1910.141(d) (1) and (2).

The two model permanent standards for Category I and Category II toxic substances require the employer to provide change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment as is presently provided by 29 CFR 1910.141. The purpose of this requirement is to reduce the possibility of an employee having skin contact with the toxic substances which collect on the employee's street clothes as a result of those clothes having been in the same storage facility as the employee's contaminated protective clothing and equipment. It should again be noted that this requirement repeats the existing obligation to provide change rooms in § 1910.-141(e) of this Part.

In addition to requiring shower facilities, the model proposed and final standards require showering at the end of each work shift. This action can, in certain cases prevent skin cancer among workers. In addition, and as importantly, it reduces the employee's overall exposure to the toxic substance. OSHA believes that, although some allege that workers currently engage in this practice, it is usually not the case. Thus, OSHA believes that it is necessary to create a legal obligation to do so, in order to assure that this practice is continued or created. The model standards also require shower facilities which comply with 29 CFR Part 1910.141(d)(3).

The model standards also require that employers assure that employees do not apply cosmetics in the regulated area. This is intended to prevent employees from sealing the toxic substance onto their skin.

OSHA invites comments on these paragraphs of the model standards. Basically, as pointed out, the additional Category I requirements to those already imposed by 29 CFR 1910.141 for hygiene facilities are capital intensive. In regulating Category II substances, OSHA is relying upon evidence insufficient to justify treating the substance as a full-blown carcinogen. Thus, the lower standard of regulation, but with what OSHA believes is an adequate margin of health and safety commensurate with the quality and quantity of evidence.

14. *Paragraph (n): Medical Surveillance.* The three model standards require that each employer institute a medical surveillance program for all employees who are, or will be, exposed to the toxic substance. OSHA believes that a medical surveillance program is appropriate in dealing with the problem of employee exposure to Category I or II toxic substances; hence, pursuant to the Act, this

standard has prescribed it. The authority, indeed the requirement, to include medical surveillance in an OSHA standard is found in subsection 6(b)(7) of the Act:

> * * * where appropriate, any such standard promulgated under subsection 6(b) shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such employment related hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure.

The three model standards require that the medical surveillance program provide each covered employee with an opportunity for medical examination. As noted above, the authority and requirement for this provision is found in section 6(b)(7) of the Act.

All examinations and procedures are required to be performed by or under the supervision of a licensed physician and provided without cost to the employee. While the physician will usually be selected by the employer, the standard does not so mandate, leaving the employer free to institute alternative procedures such as joint selection with the employee or selection by the employee. Clearly, a licensed physician is the appropriate person to be conducting a medical examination. However, certain parts of the required examination (e.g. taking of a history) do not necessarily require a physician's expertise and may be conducted by another person under the supervision of the physician. As noted above, the Congress has mandated, by reason of section 6(b)(7) of the Act, that medical examinations and procedures required by OSHA standards be provided at no cost to the employee.

The three model standards provide that a work history, medical history and medical examination be performed. The purpose of this requirement is to establish a baseline health condition against which changes in an employee's health may be compared in the detection of changes in physical condition.

The model standards leave blank the specific medical protocols for the examination. The various tests that comprise the medical examination to be prescribed in the individual rulemakings are determined by the specific toxicology and effects of each substance. The tests are designed to be used in an initial assessment of an employee's health and to detect changes in health which may occur are to be required as appropriate. Of course, if additional tests and procedures are appropriate for a given substance, they may be added in the specific rulemaking covering that substance.

The three model standards require that the employer provide the physician with certain specified information. This information includes a copy of the regulation, a description of the affected employee's duties as they relate to the employee's exposure, the results of the employee's exposure measurement, if any personal protective equipment is used or is to be used, and information from previous medical examinations of the affected employee to the extent that they are not readily available to the physician. The purpose in making this information available to the physician is to aid in the evaluation of the employee's fitness to wear personal protective equipment when required. It should be noted that the three model standards do not require that a copy of the regulation be given to the physician for each employee. One copy would be sufficient, provided the employer assures that the physician is aware of which employees are covered by this standard. Items that relate to individual employees or categories of employees (such as the description of job duties) need be transmitted to the physician only once, unless, for example, the duties change. Exposure measurements will be cumulative so that the results of each monitoring are to be sent to the physician. However, since sampling will be done on a representative basis, the language of the three model standards require the physician to be given either the employee's actual exposure measurements, if available, or the estimated level of the employee's exposure based on the relevant representative measurements.

The employer is required to obtain a written opinion from the examining physician containing: the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to the toxic substance; the results of the medical tests performed; any recommended limitations upon the employee's exposure to the toxic substance and upon the use of protective clothing and equipment such as respirators; and a statement that the employee has been orally informed by the physician of any medical conditions which require further examination or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure, and a copy of the opinion must be provided to the affected employee. The purpose in requiring the examining physician to supply the employer with a written opinion containing the abovementioned analyses is to provide the employer with a medical basis to aid in his determination of the employee's initial placement and continuing capability to use protective clothing and equipment of employees. Requiring that the opinion be in written form will serve as an objective check that employers have actually had the benefit of the information in making these determinations. Likewise, the requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the results of the medical examination and may take any appropriate action. The purpose in requiring that specific findings or diagnoses unrelated to occupational exposure not be included in the written opinion is to encourage employees to submit to medical examination by removing the fear that employers may find out information about their physical condition that has no relation to occupational exposures.

15. *Paragraph (o): Employee Information and Training.* The three model standards uniformly require the employer to provide a training program for employees exposed to the toxic substance. OSHA believes that an information and training program is essential for the protection of employees because an employee can do much to protect himself if he is informed of the nature of the hazards in his workplace. To be effective, an employee education system must, at the minimum, apprise the employee of the specific hazards associated with his work environment. For this reason, the employer would be required to inform each employee exposed to the toxic substance of the nature of the toxic substance's related health problems; the necessity for exposure control and the medical and industrial hygiene monitoring programs.

The three model standards also require that the training program be provided at least annually. The content of the training program is intended to apprise the employees of: (1) the hazards to which they are exposed; (2) the necessary steps to protect themselves, including avoiding unnecessary exposures, respiratory protection and medical surveillance; (3) their role in reducing exposures to the toxic substance and (4) their rights under the standard. Section 6(b)(7) of the Act makes it clear that these are appropriate goals of an employee training program, and the model standards, therefore, include them.

The employer is required to make a copy of the model ETS and proposed and final standards, as applicable, as well as the appendices available to the affected employees. This requirement, in combination with the review provided for as part of the training program, is intended to assure that employees understand hazards and the requirements of the applicable standard.

The employer is also required to provide, upon request, all materials relating to the training program to the Secretary and the Director. This is intended to provide an objective check of compliance with the content requirements of the applicable standard.

16. *Paragraph (p). Signs and Labels.* The three model standards require the use of signs and labels, with the two model standards for a Category I toxic substance requiring the warning of "Cancer Hazard." The model proposed and final standard for a Category II toxic substance requires the warning of "Potential Cancer Hazard." OSHA believes that it is important, and indeed section 6(b)(7) of the Act requires, that appropriate forms of warning, as necessary, be used to apprise employees of the hazards to which they are exposed in the course of their employment. OSHA believes, as a matter of policy, that employees should be given the opportunity to make informed decisions as to whether to work at a job under the particular working conditions extant. Furthermore, OSHA believes that when the control of potential safety and health problems involves the cooperation of employees, the success of such a program is highly dependent

upon the employee's understanding of the hazards attendant to that job.

In light of the serious nature of the hazard of exposure to carcinogens, OSHA does not believe that periodic training alone will adequately apprise employees of the carcinogenic hazard. However, coupled with the training requirements, OSHA believes that the requirement to post signs will adequately do so. Additionally, the appearance of the phrase "cancer hazard" or "potential cancer hazard" on the warning sign assure that employees are actually being informed of this hazard.

Since even persons who are exposed to a carcinogen only occasionally may face an increased risk of cancer, OSHA does not believe that the hazard to these people is overstated by the required signs. Also, as is the case with a regular employee, the warning signs would serve as an added impetus to occasionally visiting employees to utilize any protective equipment which has been provided.

Finally, given the evidence of the carcinogenicity of substance, OSHA believes that signs will not cause undue alarm. This is especially so when balanced against the positive results anticipated, as described above. For all of the reasons set forth, OSHA believes that it is appropriate to use precautionary signs which warn of a cancer hazard. Additionally, the phrase "authorized personnel only" relates directly to requirements in the Category I permanent standard which limit access and activities within regulated areas. (See discussions of Regulated Areas and of Hygiene Facilities and Practices.)

The words "danger" or "caution" are used for three reasons: (1) To attract the attention of workers; (2) to alert workers to the fact that they are in a dangerous area, i.e., an area where they are exposed to a potential carcinogen; and (3) to emphasize the importance of the message to follow.

The use of labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs required by this standard is permitted. OSHA recognizes that employers may be subject to various legal requirements to use warning signs and labels. The purpose of this provision of the standard is to allow the employer to comply with these various requirements in an administratively convenient manner.

The standards require that no statement which contradicts or detracts from the effect of any sign required by this paragraph shall appear on or near any such required sign. They also require that the legend on the signs be kept visible to employees by illuminating and cleaning the signs when necessary. These two requirements are designed to ensure the effectiveness of the warning signs.

Statements which contradict or detract from the intended effect of the sign are clearly counterproductive to using signs to convey information. Similarly, if the legend on the sign cannot be read because of either darkness or an unclean condition, then there is no purpose in requiring signs to be posted.

The use of precautionary labels on containers of protective clothing contaminated with the toxic substance is required. We are mindful that no evidence may presently exist that laundry workers who handle contaminated clothing containing any specific carcinogen exhibit an excess of cancer. However, no evidence exists to the contrary, and in light of our experience with other carcinogens (e.g. asbestos) and the preventative nature of the Act, we have decided to include a requirement for precautionary labels for contaminated clothing. Moreover, OSHA believes it is as appropriate that individuals who are engaged in handling and laundering the contaminated clothing be apprised of the hazard and practices to be avoided when handling the clothing as it is to inform the other primary employees.

As to labels, due to the hazardous nature of exposure to a potential carcinogen, OSHA believes that emphasis should be placed on warning employees and other persons about the danger of exposure. For this reason, the model standards include a requirement that caution labels be affixed to all containers containing the Category I and Category II toxic substance and of the products containing it, not only because of the hazardous nature of this exposure, but because of the related necessity for both the employer and employee to know whether the product contains any of the carcinogen. The labeling provisions for the model standards for the Category I and Category II toxic substance also require the employer to assure that caution labels are affixed to any product containing the toxic substance when such product leaves the employer's workplace. This proposed requirement is designed to protect any other employees who will be handling, transporting, or using this product. Thus manufacturers and suppliers would be required to affix caution labels. The rationale for this requirement is that the manufacturer or supplier is in the best position to know whether the product does contain the Category I and Category II toxic substance and should therefore be required to inform employees of even other employers of the hazards to which they are being exposed.

17. *Paragraph (g): Recordkeeping.* Section 8(c)(3) of the Act mandates the promulgation of regulations requiring employers to maintain accurate records of employee exposure to potentially toxic substances or harmful physical materials which are required to be monitored or measured. Accordingly, the three model standards contain identical provisions for recordkeeping except that the model ETS has a shorter time requirement for retention due to its short effective date and does not require a transfer of records to the Director of NIOSH if the employer ceases to do business. OSHA believes that such a requirement is not necessary for the ETS because of its short effective life (6 months).

The three model standards provide that records must be kept which include information which is intended to identify the employee and to accurately reflect the employee's exposure. Specifically, it must include: (a) the names, social security numbers and job classification of each employee covered by the monitoring, (b) the dates, number, duration and results of each of the samples taken, including a description of the representative sampling procedure used to determine employee exposure where applicable, (c) the type of respiratory protective devices worn by the employee, if any, (d) the environmental variables that could affect the measurement of employee exposure and (e) a description of the sampling and analytical methods used, and evidence of their accuracy.

The model permanent standards for both a Category I and II toxic substance require that this record be maintained for at least 40 years, or for the duration of employment plus 20 years, whichever is longer. OSHA believes that this retention period is necessary and appropriate for the development of information regarding the causes and prevention of occupational cancer related to exposure to a toxic substance. To be useful for this purpose, an exposure monitoring record must be retained long enough to allow health effects related to employee exposure to become manifest. Some of the health effects related to the development of cancer, do not become manifest for at least 20 or 30 years. Therefore, a retention period which encompasses both the period of exposure and the period of latency has been selected. Since the latency period may exceed 20 or 30 years, a minimum retention period of 40 years has been established to cover employees who have experienced shorter periods of exposure, i.e. less than 20 years.

The three model standards also require that the employer keep an accurate medical record for each employee who is subject to surveillance. Section 8(c)(1) of the Act authorizes the promulgation of regulations requiring an employer to keep such records as are necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational illnesses. OSHA believes that medical records (like exposure monitoring records) are both necessary and appropriate to both the enforcement of the standards and the development of information regarding the causes and prevention of illness related to exposure to potential occupational carcinogens.

Like all records, medical records serve as an objective check that an employer has actually performed the substantive requirements of the standard. More importantly, as explained above, it is necessary to relate employee's medical effects with their exposures in order to develop information regarding cause and prevention. Medical records are necessary and appropriate for this purpose. In addition, medical records are necessary for the proper evaluation of an individual employee's health. For all of these reasons, medical records have been required in the three model standards.

The three model standards provide that the medical records must include information which is intended to identify the employee, to accurately reflect the employee's health, and to establish that the employee has had an opportunity to participate in a medical examination. The reasons for requiring the various aspects of the medical surveillance program have been explained. It is basically these requirements which dictate the content of the medical records.

The two model permanent standards require that medical records be maintained for at least 40 years or for the duration of employment plus 20 years, whichever is greater. OSHA believes that the same justification applies to the retention period for medical records as applies to the retention of exposure monitoring records.

The three model standards require that all records required to be maintained by the recordkeeping section be made available upon request to the Assistant Secretary and Director for examination and copying. The purpose of this section is to insure compliance with the recordkeeping regulations and to provide data necessary for development of information regarding the cause and prevention of occupational cancer.

The three model standards require that employees or their designated representatives be provided access to examine and copy records of required monitoring and measuring. The purpose of this provision is to inform current employees of their exposure levels. An additional purpose for this requirement is to protect the former employee's health over his entire lifespan by permitting him access to records indicating this exposure to potentially carcinogenic substances. Section 8(c)(3) of the Act states that regulations shall provide: "employees or their representatives with an opportunity to observe * * * monitoring or measuring * * * and to have access to the records thereof." Because the final standard permits monitoring which is "representative" of an employee's exposure, not monitoring of each individual employee's exposure, the former employee can also have the right to access to all those measurements from which his exposure was determined to gain assurance that his exposure measurement was properly calculated.

The three model standards require that required employee medical records be made available upon request for examination and copying to the affected employee or former employer or to a physician designated by the affected employee or former employee. The purpose of this provision is to protect the employee's health by authorizing his designated physician to have access to medical records useful in the diagnosis of illness.

The two model permanent standards require, with regard to the transfer of records, that in the event the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained under the recordkeeping section. The purpose of this section is to assure that the records will be protected and preserved for the required retention period.

The two model permanent standards also require that in the event an employer ceases to do business and there is no successor to receive and retain the records for the prescribed period, the records are to be transmitted by registered mail to the Director of NIOSH. The purpose of this provision is to assure that records are preserved for the requisite retention period.

18. *Paragraph (r): Observation of Monitoring.* Section 8(c)(3) of the Act requires that employers provide employees or their representatives with the opportunity to observe monitoring of employee exposures to toxic substances or harmful physical agents. In accordance with this section, all three proposed model standards contain identical provisions for such observation. To assure that the right to observe is meaningful, observers would be entitled to receive an explanation of the measurement procedure, to observe all steps related to the measurement procedure and to record the results obtained.

The observer, whether an employee or designated representative, must be provided with, and is required to use, any personal protective devices required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

19. *Paragraph (s): Effective Date.* The model ETS states that it becomes effective upon publication, as provided by section 6(c) of the Act. However, certain paragraphs do contain minimally longer periods in recognition of the difficulty in requiring "instant" compliance requirements for those respective paragraphs. The two model permanent standards provide that the Agency insert the appropriate effective date during each substance-by-substance rulemaking.

20. *Paragraph (t): Appendices.* All three model standards provide for three appendices: Appendix A entitled "Substance Safety Data Sheet," Appendix B entitled "Substance Technical Guidelines" and Appendix C entitled "Medical Surveillance Guidelines". It should be noted that the appendices will be included for informational purposes only and will vary because of the differing toxicological properties of each substance. None of the statements contained therein should be construed as imposing a mandatory requirement which is not otherwise imposed or as negating any requirement which is imposed by the standard.

The information contained in Appendices A and B is intended to aid the employer in complying with requirements of the standard. This information is also to be provided to employees as part of the annual training and education program. Appendix C gives the employer a means of providing the examining physician with an explanation of the potential health effects of exposure to the toxic material and provides information needed by the physician to evaluate the results of the medical examination. Appendix C also lists other types of examinations, not required by the individual standard, which may help the physician in making an accurate determination of whether an employee should be exposed or should continue to be exposed to the toxic material.

IV. Environmental and Economic Impact Assessment

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), requires, among other things, that Federal agencies assess their proposed major actions, including proposed rulemaking, to determine whether a significant impact on the quality of the human environment may result. Furthermore, 29 CFR Part 1999.3(d) requires that where OSHA determines that an environmental impact statement should be prepared, the determination to do so must be published in the Federal Register.

At the outset, it should be pointed out that OSHA intends to issue a draft and final environmental impact statement, where warranted, in connection with each and every individual rulemaking proceeding held pursuant to this proposed Part and subpart. In addition, OSHA intends to do so within a reasonable time after the issuance of the Category I toxic substance ETS (at the time of the issuance of the proposed 6(b) model permanent standard).[10] Evaluation of the potential environmental impact of this set of regulations at this time appears to be of questionable legal

[10] OSHA does not intend to issue a draft EIS at the time a Category I ETS is promulgated but only at the time that the Category I or Category II model permanent standard is proposed. As the Court observed in Dry Color Manufacturers' Assn., Inc. v. Department of Labor, 486 F. 2d 98 (3rd Cir. 1973) at 107–08: "* * * while the NEPA requirement of an environmental impact statement applies to ordinary standards promulgated under the Occupational Safety and Health Act, an exception should be made for the Emergency Temporary Standard involved in this case. The process by which NEPA statements are produced and circulated is a lengthy one. To require its completion before the promulgation of an emergency temporary standard would impair the purpose of subsection 6(c) to provide speedy protection from grave dangers to the health of employees. No doubt any exemption of emergency temporary standards under this Act from the requirement of an environmental impact statement involves some sacrifice of the policy behind NEPA. However, that sacrifice is mitigated somewhat by the fact that an emergency temporary standard must be replaced within six months by a permanent standard, for which a completed impact statement is required, and it is, in any case, justified by the need to accommodate the provisions of NEPA with those of the Occupational Safety and Health Act. We therefore have concluded that where, as here, OSHA begins the process contemplated by NEPA by issuing a draft environmental impact statement within a reasonable time after issuing an emergency temporary standard, the requirements of NEPA are sufficiently satisfied." OSHA intends in the future, and has in the past, followed exactly that procedure.

necessity and value. This is so because until the proposal is implemented on a substance-by-substance basis, there can be little, if any, precise quantitative assessment of environmental impact. Such an attempt at this time must necessarily be highly speculative because of unknown substances and unidentified industries. Nevertheless, OSHA has attempted to evaluate the elements of environment impact to the limited extent possible at this time. OSHA intends that the preceding description of the proposed standard, together with its supporting rationale, which relate primarily to the workplace environment, as well as the following section on external environmental impact, do constitute a draft environmental impact statement on this proposed set of regulations concerning the identification, classification, and regulation of potential carcinogens.

This statement has been prepared in accordance with the provisions of NEPA as well as the guidelines of the Council on Environmental Quality (40 CFR Part 1500). The purpose of this draft environmental impact statement, however, is to aid in OSHA's decision making on proposed actions which may have the potential for significantly affecting the quality of the human environment, and, hopefully, for the better. Written comments and information on the projected impacts of this proposed set of regulations, as well as the desirability of preparing an environmental impact statement at this time, are solicited from any interested persons or groups during the period for written comment submissions listed below in this Notice. In issuing the final set of regulations pursuant to this subpart, OSHA will determine whether a final environmental impact statement is required. In addition, prior to the hearing, OSHA will determine if it has facts not before it at present to amend or revise this draft environmental impact statement.

In addition to this general request for comment, copies of this proposal and draft environmental impact statement will be sent to numerous Federal and State agencies, industry representatives, employee unions, and public interest groups with requests for their comments. A copy of this listing is available in the OSHA Technical Data Center, Room S–6212, Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210.

Testimony, data, arguments, and related submissions on environmental impact will be received at the public hearing to be held on this proposed set of regulations on March 14, 1978, provided prehearing submission requirements, also outlined below, are complied with.

Additional copies of this draft environmental impact statement are available for review and copying in the OSHA Technical Data Center.

A. ALTERNATIVES

There appear to be at least three major areas of regulatory decision making which will affect the impact of this proposed Part and subpart on the external environment. These are: (1) the scope and application of the applicable model standard, (2) the airborne permissible exposure limits, and (3) the methods by which compliance is mandated. The purpose of this section is to present the alternatives available. The discussion of the impact of each of these alternatives will be in the following section. At the outset however, it should be noted that the impacts on the workplace environment will be beneficial ones, with fewer cases of cancer in the years to come. This preamble details some of the studies and reports on which OSHA bases its belief that this beneficial impact will occur. Further, it is anticipated that more information concerning the proposal's potential for impacting the workplace environment will be introduced during the course of the public comment and hearing period of this rulemaking proceeding.

(1) *Scope and Application.* The three model standards apply to those industries or classes of operations that OSHA determines, in the individual rulemakings conducted pursuant to this proposal Part and subpart, should be regulated. Likewise, this proposal provides an exemption for those industries or classes of operations that OSHA has decided not to include, for the reasons stated in the respective preambles, in those subsequent rulemakings concerning individual toxic substances. As pointed out below, OSHA presently has no data which would quantify the impacts of those subsequent rulemakings as to regulation of toxic substances that will be classified as Category I or Category II toxic substances. Some alternatives would be to provide for no exemption on the one hand or limit application only to industries of major exposure on the other.

(2) *Permissible exposure limits.* The proposed Part and subpart propose that for Category I toxic substances, the permissible exposure limits shall be reduced to the lowest levels feasible, except in cases where suitable, less hazardous substances are available, in which case no occupational exposure is permitted. The model ETS and permanent standard for a Category I toxic substance also prohibit eye contact and skin contact to the toxic substance. The model permanent standard for a Category I toxic substance also prohibits a ceiling level of more than 5 times the airborne 8 hour time-weighted average.

The permissible exposure limits for Category I toxic substances are not chosen as "safe" or "no-effect" levels, but on the basis of OSHA's belief as to the lowest feasible levels. OSHA is mandated by the Act to consider feasibility in setting regulations. However, it is possible that after each such rulemaking contemplated by this proposed Part and Subpart, that a level lower than that set in the ETS or the proposed model standard could be shown to be feasibly attained either by existing controls or by the development of new controls. In that case, OSHA has the option to regulate to whatever level is determined to be appropriate. Likewise, where the proposed level in the model permanent standard is shown to be infeasible to achieve, a higher figure may appear in the final standard.

As has been pointed out, in the case of the Category II toxic substances, present permissible exposure levels are retained where OSHA presently has a standard, sets permissible exposure limits where no OSHA standard presently exists or lowers the exposure limits found in a present OSHA standard where it can be shown that such levels do not protect against acute and chronic effects other than carcinogenicity.

Another regulatory alternative is to adopt differing standards for different industries, moderating the degree of regulation as deemed necessary for adequate and feasible protection of workers in the various industries where exposure to the Category I and Category II toxic substance exists.

In any event, regardless of the alternative chosen, the impacts of an OSHA regulation for a carcinogen can be summarized as follows: the more of the toxic substances emitted from the workplace into the air or into water systems, the greater the potential for adverse impacts on air and/or water quality. Depending upon the levels of the toxic substance present in the ambient air and water of communities surrounding regulated workplaces, however, better control of exposures in the workplace may have the potential for benefiting the general human environment of nearby areas as a result of limiting fugitive emissions and controlling point source emissions. In any event, in the case of Category I toxic substances, reduction of employee exposure to levels lower than that presently required under the current standard (29 CFR 1910.1000) or lower than present levels where no such standard exists at all should, have a beneficial impact upon the external environment as well. The same can be said for the regulation of Category II toxic substances where the permissible exposure limits can remain the same or be reduced.

(3) *Methods of Compliance.* OSHA's present regulation in 29 CFR 1910.1000, under which exposure levels for certain toxic materials have been set, provide that compliance be achieved first through administrative or engineering controls, where feasible, and, when such controls are not feasible, through the use of supplementary protective equipment.

The two model permanent standards (as distinct from the ETS) require the institution of engineering and work practice controls to reduce exposure to or below the permissible exposure limits. In addition, the proposal requires that a program be established and implemented to reduce exposures to or below the permissible exposure limits, solely by means of engineering and work practice controls. Protective clothing and equipment are also required where necessary to prevent eye contact or repeated skin contact.

Engineering controls may include the installation of local exhaust ventilation, modification of a process so as to reduce

emission, or substitution of a less hazardous substance.

Alternatives involved in the compliance section of the regulation are primarily concerned with establishing a particular priority among the types of controls (engineering, work practice, and respiratory protective equipment). Sole reliance on engineering controls or on use of engineering and work practices equally could be required. Another alternative would allow the employer complete freedom in choosing the method of control without any required priority systems.

Additionally, there are other areas in which alternative actions might variously have impact upon what is considered the external environment. One of these areas is medical surveillance. The proposed ETS provides, in general, for the minimum tests considered necessary over the short life of that standard. The two model permanent standards require, in general, a more comprehensive evaluation and perhaps a more sensitive means of detecting changes which may indicate effects of exposure to the individual toxic substances.

The possible impacts of these approaches will be discussed in the following chapter.

B. PROJECTED IMPACTS

The primary effect of this Part and subpart, as implemented in the subsequent substance-by-substance rulemakings that follow, is expected to impact on the workplace by reducing worker exposure to Category I and Category II toxic substances. A second potential impact may occur to the environment external to the workplace.

The impacts on workers and the work environment of this proposed set of regulations has already been treated above. This section attempts, to the best possible extent, to delineate the impacts of this Part and subpart on the external environment and will also consider the potential impacts of alternative regulatory measures and various compliance methods. It should be remembered that, where required, OSHA intends to develop an environmental impact statement where Category I and Category II toxic substances are classified in the individual rulemakings.

A standard for control of occupational exposure to a carcinogen has the potential for affecting the external air quality, water quality, waste disposal (a function of land use, air quality and water quality), energy consumption, and human resources. Economic costs of implementing an occupational health standard also has been determined to have the potential for impacting the general human environment.

The specifics of potential impacts, expected as a result of the promulgation of this proposed Part and subpart, cannot, as pointed out, be foreseen and is somewhat speculative. An overview however gives a general idea of some of the types of impacts which may result, and the ways in which they depend on the various alternatives involved in the regulatory decisionmaking and subsequent choice of compliance methods.

The first area of alternatives is in the scope and application of the subsequent rulemakings pursuant to this proposed Part and subpart. If, for some explained reason, a substantial industry or use were excluded from the scope of the standard, there might be little if any impact upon the external environment. The basic direction of the impacts would appear to be improvement of the ambient air quality by reduction of contamination of the employees' breathing air. It would also appear easier to control contamination of the external environment by converting non-point source emissions into point sources.

To the extent that monitoring and medical surveillance of employees is required, there will be an impact on medical resources and the supply of industrial hygienists. The full extent of this impact cannot be readily quantified although the incidence of cancer avoidance may ultimately lead to less demand upon such resources.

The second area of alternative is in setting the permissible exposure limits. This area is integrally related to the methods of compliance (the third area of alternatives) used to achieve control of exposure to or below the permissible exposure limits. The choice of alternative levels of exposure compliance is expected to have impact in some way every category of the external environment.

In a general sense, reduction of exposure to liquid toxic substances will involve enginering control to prevent emissions at the source, work practices to prevent accidental spills and contacts and good housekeeping procedures to cope with spills when they do occur.

In the case of dust, if control of employee exposures are achieved, for example, by methods which collect the exhausted fumes, dust, vapors, etc. of the toxic substance, logically, air quality in the neighborhood surrounding workplaces containing the toxic substance may be improved. Similarly, the method of dust collection and disposal could impact water quality, solid waste and land use categories.

Respirators may also be used in some cases to prevent worker exposure to dust, vapor, etc. An additional method of compliance might be the substitution of some other substance.

The extent of engineering control required is to some extent relative to the level of exposure which must be met. If exposure is to be controlled by preventing leaks and evaporation, then the controls would have to be tighter and perhaps more extensive to meet lower exposure limits. This would result in less workplace contamination and, thereby, lower ambient emissions. On the other hand, if control is achieved by ventilation, the amount of contamination by the toxic substance would remain constant but the rate of exhaust outside the plant would increase. This increased flow rate may not affect the ambient air quality, but might result in an insignificant increase in energy consumption.

Likewise, tighter engineering controls to achieve lower levels of exposure escape of the toxic substance into the effluent discharge, represent a positive impact on water quality. Conversely, other means of control and their degree of effectiveness may result in increased contamination of water and increased sludge production, representing a potential negative impact on both water quality and the amount of solid waste. The exposure levels and compliance methods chosen should have no effect on the amount of monitoring and medical surveillance required. However, the degree of impact on human resources will depend on the contents of monitoring and medical surveillance provisions.

In sum, as pointed out, OSHA has little data which quantify these potential impacts but will issue an EIS, where required, in the case of each individual rulemakings held pursuant to this proposed Part and subpart. Submissions and public comment into the record of this proceeding concerning this issue are encouraged. Likewise, OSHA believes that potential impacts upon human resources, energy, land use and other economic aspects posed by the proposed set of regulations cannot readily be quantified, except in the individual environmental impact statements prepared and issued at the time of the substance-by-substance rulemakings pursuant to this proposed part and subpart.

C. RELATIONSHIP WITH OTHER FEDERAL ACTIONS

Workers exposed to a toxic material during industrial operations constitute that portion of the general population most exposed to its health hazards. Any OSHA standard to limit occupational exposure to that toxic material is written for their protection. However, since workers are exposed in a variety of industries and because many toxic materials may be released to the general environment and have impacts on the consumer and the environment external to the workplace this rulemaking is also a matter of concern to EPA, CPSC and FDA. OSHA intends to coordinate its activities with these and other agencies in this and the subsequent rulemakings.

D. ECONOMIC IMPACT ASSESSMENT

The Assistant Secretary of Labor for Occupational Safety and Health has determined that economic impact assessments, as applicable, will be performed pursuant to Executive Orders 11821 (39 FR 41501) and 11949 (42 FR 1017) in the individual rulemakings to be conducted pursuant to this Part and subpart, where it is possible to consider such impacts.

V. PUBLIC PARTICIPATION; NOTICE OF HEARING

On January 20, 1977, the Assistant Secretary of Labor for OSHA transmitted for review and comment a draft of this proposed set of regulations, and preamble, to the National Advisory Com-

mittee on Safety and Health (NACOSH), a standing advisory committee provided for by section 7(a) of the Act.

After several subcommittee meetings, which were duly announced in the FEDERAL REGISTER, to discuss the draft preamble and regulations, the two relevant NACOSH subcommittees, one the subcommittee on Standards and the other on Policy and Budget, on April 5, 1977, adopted their position which was received and adopted by the full NACOSH committee on May 5, 1977. The resolution stated:

RECOMMENDATIONS ON PROPOSED REGULATION OF CERTAIN TOXIC MATERIALS

Having reviewed the draft document "Regulation of Certain Toxic Materials", we endorse OSHA's general attempt to deal with this difficult problem. In order to develop in the public forum the various factors, including certain legal and scientific issues, for a regulatory carcinogen policy to govern OSHA's administrative approach and to proproposal should be published in the FEDERAL REGISTER solely for the purpose of information gathering and that neither the document nor the process be engaged for a rulemaking purpose at this time. This recommendation is proposed since:

1. The document can be adopted by OSHA as an administrative policy, and there should be such flexibility.

2. The document, even if adopted as a policy through the rulemaking process, would not deprive due process challenges when subsequent standards are promulgated.

3. The document identifies those issues upon which much debate has evolved and should continue, including the concept that some substances, although not always scientifically definable as carcinogens, must be addressed because of a regulatory obligation.

ISSUES WHICH NEED TO BE EXPANDED

1. Address adequacy of classification system.
2. Address carcinogenicity of impurities and mixtures.
3. Expand discussion on "other than animal testing" routes.
4. Anatomic and metabolic fate.
5. Decision on rate retention issue.

OSHA has carefully reviewed NA COSH's recommendations. Because of importance of the issues raised herein and in order to assure participation in resolution of these issues and maximum usefulness of the cancer policy once adopted, OSHA believes that it should commence this rulemaking at this time with the full procedures provided for in section 6(b) of the Act. The alternative could well be an internal pronouncement of policy which might effect substantive rights of interested parties and therefore not be sustainable in the Courts, thus, in actuality delaying its effective date in this important area by years.

Interested persons are invited to submit written data, views and arguments on this proposed Part, subpart and all issues raised or involved herein. These comments must be postmarked on or before December 8, 1977 and must be submitted in quadruplicate to the Docket Officer, Docket No. H–090, Room S–6212, U.S. Department of Labor, 3rd Street and Constitution Avenue NW., Washington, D.C. 20210. Written submissions must clearly identify the provisions of the proposal addressed and the position taken with respect to each such provision. The data, views, and arguments will be available for public inspection and copying at the above address. All written submissions received will be made a part of the record of this proceeding.

In order to expedite this rulemaking proceeding and in anticipation of requests for a hearing, OSHA is scheduling an informal public hearing, pursuant to section 6(b)(3) of the Act and 29 CFR Part 1911, to begin on March 14, 1978 in the Department of Labor Auditorium, 3rd Street and Constitution Avenue NW., Washington, D.C.

All issues raised in this notice and all aspects of the proposed set of regulations including OSHA's views on its economic and environmental impacts, will be at issue in the hearing.

NOTICES OF INTENTION TO APPEAR

All persons who desire to participate at the hearing must file a notice of intention to appear, postmarked on or before December 8, 1977 with the OSHA Office of Consumer Affairs, Room N3633, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210 (Telephone: 202–523–8023). The notices of intention to appear, which will be available for inspection and copying at the above address, must contain the following information:

(1) The name, address and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The aproximate amount of time required for the presentation;

(4) The specific issue raised by the proposal that will be addressed;

(5) A detailed statement of the position that will be taken with respect to each issue addressed; and

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence.

FILING OF TESTIMONY AND EVIDENCE BEFORE HEARING

Any party requesting more than 15 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of testimony, including any documentary evidence to be presented at the hearing, to the OSHA Division of Consumer Affairs. This material must be received by January 9, 1978, and will be available for inspection and copying at the Technical Data Center—Docket Office. Each such submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 15 minute presentation, and may be requested to return for questioning at a later time.

Testimony of witnesses to be called by OSHA will be filed and made available to the public on or before February 28, 1978.

CONDUCT OF THE HEARING

The hearing will commence at 9:30 a.m. on March 14, 1978 and will be conducted in accordance with 29 CFR Part 1911. The oral proceedings will be reported verbatim and a transcript will be made available for inspection and copying to interested persons.

The Administrative Law Judge, who will be designated to preside at the hearing, shall have all the powers necessary or appropriate to conduct a fair and full informal hearing, including the powers;

(1) To regulate the course of the proceedings;

(2) To dispose of precedural requests, objections, and comparable matters;

(3) To confine presentations to matters pertinent to the proposed standard;

(4) To regulate the conduct of those present at the hearing by appropriate means;

(5) In his discretion, to question and permit questioning of any witness; and

(6) In his discretion, to keep the record open to receive written information and additional data, views, and arguments from any person who has participated in the oral proceedings.

Following the close of the hearing, the presiding Administrative Law Judge shall certify the record thereof to the Assistant Secretary of Labor for Occupational Safety and Health. The proposal will be reviewed in light of all the oral and written submissions received as part of the record in this proceeding and appropriate action will be taken.

VI. AUTHORITY

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210.

Accordingly, pursuant to sections 4(b), 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 1599; 29 U.S.C. 653, 655, 657), the Secretary of Labor's Order 8–76 (41 FR 25059) and 29 CFR Part 1911, it is hereby proposed to amend Title 29, of the Code of Federal Regulations, by adding a new Part 1990, to identify, classify, and regulate certain toxic substances, as set forth below.

Signed at Washington, D.C., this 28th day of September 1977.

EULA BINGHAM,
Assistant Secretary of Labor.

A new Part 1990, and certain subparts thereto, are proposed to be added to Title 29 of the Code of Federal Regulations, reading as follows:

PART 1990—IDENTIFICATION, CLASSIFICATION AND REGULATION OF CERTAIN TOXIC SUBSTANCES

Subpart A—General

Sec.
1990.1 Scope
1990.2 Purpose.

Subpart B—Identification, Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk

GENERAL

1990.101 Scope.
1990.102 Definitions.
1990.103 Classification of substances.
1990.104 Advisory committees.

CATEGORY I TOXIC SUBSTANCES

1990.110 Category I Toxic substances.
1990.111 Rebuttal of a Category I classification to a category II or III classification.
1990.112 Consequences of a category I classification.
1990.113 Limitation of issues in the rulemaking.
1990.114 Final action after a category I rulemaking.

CATEGORY II TOXIC SUBSTANCES

1990.120 Category II Toxic substances.
1990.121 Rebuttal of a category II classification to a category III classification.
1990.122 Consequences of a category II classification.
1990.123 Limitation of issues in the rulemaking.
1990.124 Final action after a category II rulemaking.

CATEGORY III TOXIC SUBSTANCES

1990.130 Category III toxic substances.
1990.131 Consequences of a category III classification.
1990.132 Reconsideration of a category III classification.
1990.133 The category III toxic substances list.

CATEGORY IV TOXIC SUBSTANCES

1990.140 Category IV toxic substances.
1990.141 The category IV toxic substances list.

MODEL STANDARDS

1990.150 Section 6(c) model standard for a category I toxic substance.
1990.160 Section 6(b) model standard for a category I toxic substance.
1990.170 Section 6(b) model standard for a category II toxic substance.

Subpart C—Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Teratogenic Risk [Reserved]

Subpart A—General

§ 1990.1 Scope.

This Part provides for the identification, classification and regulation of certain toxic materials, pursuant to the Occupational Safety and Health Act of 1970 (the Act), as set forth in the various subparts below.

§ 1990.2 Purpose.

The Act provides, among other things, that "the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired". (Section 6(b)(5).) It is the purpose of the regulations of this Part to carry out the intent of the Act.

Subpart B—Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk General

§ 1990.101 Scope.

This subpart provides for the identification, classification and regulation of toxic substances which pose an occupational carcinogenic risk to workers.

§ 1990.102 Definitions.

Terms used in this subpart shall have the meanings set forth in the Act. In addition, as used in this subpart, the following terms shall have the meanings set forth below:

"Act" means the Occupational Safety and Health Act of 1970 (Pub. L. 91–596, 84 Stat. 1590 *et seq.*).

"Administrator of EPA" means the Administrator of the United States Environmental Protection Agency, or designee.

"Chairman of CPSC" means the Chairman of the United States Consumer Product Safety Commission.

"Commissioner of FDA" means the Commissioner of the Food and Drug Administration, United States Department of Health, Education, and Welfare or designee.

"Director of NCI" means the Director of the National Cancer Institute, United States Department of Health, Education, and Welfare, or designee.

"Director of NIOSH" means the Director of the National Institute for Occupational Safety and Health, United States Department of Health, Education, and Welfare, or designee.

"Foreign toxic substance" means any toxic material that would meet the definition of a toxic substance, except that it is not found in the American workplace.

"Mutagenesis" means the property of a toxic material to induce changes in the genetic material of either somatic or germinal cells or tissues in subsequent generations.

"Potential occupational carcinogen" means any toxic substance which (1) Causes, at any level of exposure or dose, as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the systemic distribution of the substance under consideration, in the organism tested, an increased incidence of benign or malignant neoplasms, or a combination thereof, in (i) humans or (ii) in one or more experimental mammalian species, or (2) in a statistically significant manner decreases the latency period between exposure and onset of neoplasm in (i) humans or (ii) in one or more experimental mammalian species.

"Secretary" means the Secretary of Labor, or designee.

"Short-term tests" includes, but is not limited to positive results in more than one of the following assays for: (1) the induction of DNA damage and repair; (2) mutagenesis in bacteria, yeast, or *Drosophila melanogaster*; (3) mutagenesis in mammalian somatic cells; (4) mutagenesis in mammalian germinal cells; or (5) positive results in tests for neoplastic transformation of mammalian cells in culture.

"Suggestive" means that degree of confidence in test animal or human data which is less than persuasive or not statistically significant but which, nonetheless, raises scientific concerns that the toxic substance may pose a carcinogenic risk to the exposed animals or humans.

"Toxic substance", for the purposes of this subpart, means any toxic material, found in the American workplace, either a single chemical substance or combination of substances, or any other agent, which has been reported by scientific study, at any level of exposure or dose, as the result of any exposure, to (1) Cause neoplasms, benign or malignant, in (i) humans or (ii) in one or more experimental mammalian species, or (2) In a statistically significant manner decreases the latency period between exposure and onset of neoplasms, in (i) humans or (ii) in one or more experimental mammalian species.

§ 1990.103 Classification of substances.

(a) *General.* (1) Whenever the Secretary receives information, submitted to him in writing by any interested person, concerning any toxic substance, or upon his own cognizance has any such information, he shall, to assist him in developing information relevant to the classification of a toxic substance: (i) Within thirty (30) days publish a notice of receipt in the FEDERAL REGISTER, together with a short statement identifying the contents and sources of such information, and shall provide a period for public comment, except as provided by (a)(2) herein, or (ii) Where the Secretary certifies in writing to the interested party that information exists that additional scientific data or study that may be relevant to the classification of a toxic substance is not immediately available or does not yet exist but will be available within a short period of time, the Secretary may delay the publication date of receipt of the original

information in the FEDERAL REGISTER referred to but in no case shall the publication date be extended to more than one hundred and eighty (180) days after the receipt of the original information.

(2) The period for public comment provided for by § 1990.103(a)(1) shall be at least thirty (30) days but not more than sixty (60) days unless the Secretary determines issued that extraordinary circumstances warrant less or no time for such public comment.

(b) *Classification.* Within thirty (30) days from the close of the comment period, or from the receipt of the report of an Advisory Committee as provided by § 1990.104, the Secretary shall classify or reclassify the toxic substance in accordance with the criteria set forth in this subpart and publish in the FEDERAL REGISTER a notice of his decision as to the classification of that substance, together with the other consequences and actions required by this subpart.

(c) *Reclassification.* As to toxic substances previously classified pursuant to this subpart, the term "information" as used by § 1990.103(a) is limited to additional evidence, not reviewed at the time of the issuance of the final standard, or to a new scientific review of the then existing evidence.

§ 1990.104 Advisory committees.

At any time the Secretary decides to appoint an advisory committee, pursuant to sections 6(b) and 7 of the Act, to assist him in his standard-setting function concerning any toxic substance, he shall require that the advisory committee submit to him its recommendations regarding the rule to be promulgated no later than ninety (90) days from the date of its appointment.

CATEGORY I TOXIC SUBSTANCES

§ 1990.110 Category I toxic substances.

A presumption exists that a toxic substance shall be classified by the Secretary as a "Category I Toxic Substance" if: (a) the toxic substance meets the definition of a "potential occupational carcinogen" in (1) humans, or (2) two mammalian test species, or (3) a single mammalian species, if those results have been replicated in the same species in another experiment or (4) a single mammalian species if those results are supported by short-term tests, or (b) the Secretary finds that any other evidence is sufficient to convince him that the toxic substance should be classified as a Category I Toxic Substance.

§ 1990.111 Rebuttal of a category I classification to a Category II or III classification.

(a) The presumption that a toxic substance be classified as a Category I toxic substance shall be rebutted if the Secretary determines, after consultation with the Director of NIOSH, that scientifically:

(1) The carcinogenic evidence based on animal data clearly resulted from physical, rather than chemical induction; or

(2) The route of exposure in animals is grossly inappropriate relative to the potential occupational routes of human exposure, or

(3) The human or animal data relied upon are only suggestive, or

(4) The human or animal data relied upon are totally inadequate to establish any conclusion with respect to the carcinogenicity or non-carcinogenicity of the toxic substance; or

(5) For some other reason, the positive results in the experimental animal species are not scientifically relevant to man insofar as the toxic substance in question is concerned.

(b) Such determinations and reasons shall be in writing and published in the FEDERAL REGISTER, pursuant to section 1990.103, and shall classify the substance as a Category II toxic substance if the determination was based on § 1990.111(a)(3) in that the Secretary has determined that the human or animal studies relied upon are only suggestive. All other toxic substances for which the Secretary has determined that a Category I classification is inappropriate shall be classified as a Category III toxic substance.

§ 1990.112 Consequences of a category I classification.

In the event the Secretary determines that a toxic substance shall be classified as a Category I Toxic Substance, he shall require the initiation of the following actions:

(a) He shall, at the time he classifies the toxic substance as Category I, issue an Emergency Temporary Standard, pursuant to section 6(c) of the Act, which shall follow the format and content of the model emergency temporary standard set forth in § 1990.150. Any deviation, addition or change from that format or content shall be explained, together with the reasons therefor.

(b) He shall, within sixty (60) days from such classification, issue a notice of proposed rulemaking, pursuant to section 6(b) of the Act, which shall follow the format and content of the model standard set forth in § 1990.150. Any deviation, addition or change from that format or content shall be explained, together with the reasons therefor. The permissible exposure limits, insofar as the proposed standard is concerned, shall be set as low as feasible. When it is determined by the Secretary that there are suitable substitutes for certain uses or classes of uses that are less hazardous to humans, on the basis of the best available evidence, the proposal shall permit no occupational exposure for such uses or classes of uses.

§ 1990.113 Limitation of issues in the rulemaking.

At any time after a request for a public hearing is made or upon his initiative, subsequent to the publication of the documents referred to in § 1990.112, the Secretary shall provide for such a hearing in accordance with Section 6(b) of the Act, the regulations thereunder and 29 CFR Part 1911. The issues in the hearing or in comment shall be limited to the following: (a) Whether the Secretary correctly classified the toxic substance according to the Category I criteria (§ 1990.110); (b) whether the Secretary was correct in his determination that the Category I classification should not be rebutted (§ 1990.111); (c) the determination of the lowest feasible occupational exposure, or whether there are suitable substitutes that are found to be less hazardous to humans than the toxic substance; (d) whether the toxic substance has unique properties or uses that make the specific protective measures of the proposed standard inappropriate or infeasible; and (e) the environmental impact arising from regulation of the toxic substance.

§ 1990.114 Final action after a category I rulemaking.

(a) *Affirmance.* At the conclusion of the Category I rulemaking, if the Secretary determines, based on the record, that his classification of the toxic substance as Category I was correct and that his decision not to rebut the presumption was also correct, he shall issue a standard which shall follow the format and content of the model standard contained in § 1990.160. Any deviation, addition or change from that format and content shall be explained, together with the reasons and evidence therefor. However, the permissible exposure level shall be set as low as feasible or, when it is determined by the Secretary that there are suitable substitutes that are less hazardous to humans, on the best available evidence, no occupational exposure shall be permitted for that use or class of use.

(b) *Change in classification.* At the conclusion of the Category I rulemaking, if the Secretary determines, based on the record, that his classification of the toxic substance as a Category I Toxic Substance was incorrect, or that his decision not to rebut the presumption was incorrect, he shall classify the toxic substance as a Category II or III Toxic Substance, as follows:

(1) If the Secretary determines that the toxic substance should have been classified as a Category II Toxic Substance, he shall issue a final standard which shall follow the format and content of the model standard contained in § 1990.170. Any deviation, addition or change from that format and content shall be explained, together with the reasons therefor.

(2) If the Secretary determines that the toxic substance should have been classified as a Category III Toxic Substance, he shall follow the procedures provided by § 1990.131.

CATEGORY II TOXIC SUBSTANCES

§ 1990.120 Category II toxic substances.

A toxic substance shall be classified by the Secretary as a "Category II Toxic Substance" if the toxic substance meets the definition of a "potential occupational carcinogen" in studies in test animals or humans, the results of which, however, were found by the Secretary,

pursuant to § 1990.111(a)(3), to be only suggestive. This classification is required and is not presumptive. In addition, a presumption exists that a toxic substance shall be classified by the Secretary as a "Category II Toxic Substance" if: (a) The toxic substance meets the definition of a "potential occupational carcinogen" in an unreplicated experiment in a single mammalian test species or (b) the Secretary finds that any other evidence is sufficient to convince him that the toxic substance should be classified as a Category II Toxic Substance.

§ 1990.121 Rebuttal of a category II classification to a category III classification.

(a) The presumption that a toxic substance be classified as a Category II toxic substance shall be rebutted if the Secretary determines, after consultation with the Director of NIOSH, that scientifically:

(1) The carcinogenic evidence based on the animal data clearly resulted from physical, rather than chemical induction, or

(2) The route of exposure in animals is grossly inappropriate relative to the potential occupational routes of human exposure, or

(3) The animal data in a single mammalian test species is less than suggestive; or

(4) For some other reason, the positive results in the experimental animal species are not scientifically relevant to man insofar as the toxic substance in question is concerned.

(b) Such determinations and reasons shall be in writing and published in the FEDERAL REGISTER, pursuant to § 1990.103, and shall classify the substance as a Category III toxic material.

§ 1990.122 Consequences of a category II classification.

In the event the Secretary determines that a toxic substance shall be classified as a Category II Toxic Substance, he shall require the initiation of the following actions:

(a) He shall, within sixty (60) days from the announcement of his intent to classify the toxic substance as a Category II toxic substance, issue a notice of proposed rulemaking, pursuant to section 6(b) of the Act, which shall follow the format and content of the model standard set forth in section 1990.170. Any deviation, addition or change from that format or content shall be explained, together with the reasons therefor. The permissible exposure limits, insofar as the proposal is concerned, shall be: (1) the present OSHA standard or (2) where none exists, an appropriate level based upon acute or chronic effects of exposure to the toxic substance other than carcinogenicity or (3) where acute or chronic effects indicate that the present OSHA standard is inadequate, the exposure level shall be lowered to the level found appropriate by the Secretary. He shall also give notice that if, pursuant to the rulemaking, it is determined that the toxic substance should be classified as a Category I toxic substance, the final standard will be that required by 1990.160 herein.

(b) He shall notify the applicable federal and state agencies, including the Administrator of EPA, the Director of NCI, the Director of NIOSH, Commissioner of FDA and the Chairman of CPSC of the determination that the evidence is "only suggestive" or that the evidence consists of only positive results in one mammalian species and request that the applicable agencies engage in, or stimulate, further research pursuant to their legislative authority, to develop new and additional scientific data.

§ 1990.123 Limitation of issues in the rulemaking.

At any time after a request for a public hearing is made or upon his initiative, subsequent to the publication of the documents referred to in § 1990.122, the Secretary shall provide for such a hearing in accordance with section 6(b) of the Act, the regulations thereunder and 29 CFR Part 1911. The issues in the hearing or in comment shall be limited to the following: (a) Whether the Secretary correctly classified the toxic substance according to the Category II criteria (§ 1990.120); (b) Whether the Secretary was correct in his determination that the Category II classification should not be rebutted (§ 1990.121); (c) If OSHA presently has no standard, or it is inadequate based on considerations of acute or chronic effects other than carcinogenicity, the appropriate level of exposures; (d) Whether the toxic substance has unique properties or uses that make the specific protective measures of the proposed standard inappropriate or infeasible; and (e) the environmental impact arising from regulation of the toxic substance.

§ 1990.124 Final action after a category II rulemaking.

(a) *Affirmance.* At the conclusion of the Category II rulemaking, if the Secretary determines, based on the record, that his classification of the toxic material as Catetgory II was correct and that his decision not to rebut the presumption was also correct, he shall issue a standard which shall follow the format and content of the model standard contained in § 1990.170. Any deviation, addition or change from that format and content shall be explained, together with the reasons and evidence therefor.

(b) *Change in classification.* At the conclusion of the Category II rulemaking, if the Secretary determines, based on the record, that his classification of the toxic substance as a Category II Toxic Substance was incorrect, or that his decision not to rebut the presumption was incorrect, he shall classify the toxic substance as a Category I or Category III Toxic Substance, as follows:

(1) If the Secretary determines that the toxic substance should have been classified as a Category I Toxic Substance, he shall issue a standard which shall follow the format and content of the model standard contained in § 1990.160. Any deviation, addition or change from that format and content shall be explained, together with the reasons therefor.

(2) If the Secretary determines that the Toxic Substance, should have been classified as a Category III Toxic Substance, he shall follow the procedure provided by § 1990.131.

CATEGORY III TOXIC SUBSTANCES

§ 1990.130 Category III toxic substances.

Any toxic substance not classified by the Secretary as a Category I or a Category II toxic substance, pursuant to this subpart, shall be classified as a Category III Toxic Substance.

§ 1990.131 Consequences of a category III classification.

(a) At the time a toxic substance is classified as Category III, the Secretary shall transmit his findings to the Director of NCI, the Director of NIOSH, the Administrator of EPA, the Commissioner of FDA, and the Chairman of CPSC with a request that each determine whether there is additional information, previously unavailable to, or unreviewed by, the Secretary, which could have a bearing on reconsideration of the Category III classification of the toxic substance.

(b) The determination that a Toxic Substance is classified by the Secretary as a Category III Toxic Substance shall be published and appropriately updated in the FEDERAL REGISTER and the Code of Federal Regulations.

§ 1990.132 Reconsideration of a category III classification.

If, at any time, any of the agencies, referred to in Section 1990.131, provide additional information having a bearing on the initial determination of classification, the Secretary shall, within thirty (30) days after the receipt of such a response, publish in the FEDERAL REGISTER the response and reconsider his decision to classify the toxic substance as Category III.

§ 1990.133 The category III toxic substance list.

The following substances have been determined by the Secretary to be Category III toxic substances for the purposes of this subpart. They are:

Name:	*Federal Register date of final publication*
1. Water	Aug. 26, 1977

CATEGORY IV TOXIC SUBSTANCES

§ 1990.140 Category IV toxic substances.

(a) Notwithstanding any other provision of this subpart, whenever the Secretary determines after consultation with the Administrator of EPA, the Director of NIOSH, the Director of NCI, the Commissioner of FDA and the Chairman of CPSC that a toxic material would meet the definition of a toxic substance except that it is not found in the American workplace and therefore meets the definition of a foreign toxic

substance, he shall publish in the FEDERAL REGISTER a notice of his intent to classify the foreign toxic substance as a Category IV Toxic Substance and shall provide a period of at least thirty (30) days but not more than sixty (60) days for public comment.

(b) Within thirty (30) days from the close of the comment period, or from the receipt of the report of an Advisory Committee as provided by § 1990.104, the Secretary shall classify the foreign toxic substance as a Category IV Toxic Substance and list such foreign toxic substance in § 1990.141 hereof or, if he determines that his original intent was in error, the Secretary shall initiate the procedures required by § 1990.103(a) *et seq.* hereof.

(c) The determination that such toxic substance is not found in the American workplace shall be published and appropriately updated in the FEDERAL REGISTER and Code of Federal Regulations.

(d) Whenever the Secretary receives information, submitted to him in writing by any interested person, or upon his own cognizance has any information, that such toxic substance previously classified as a Category IV toxic substance is, has been, or will be found in an American workplace, the Secretary shall, within thirty (30) days, initiate the procedures required by § 1990.103(a) *et seq.* hereof.

§ 1990.141 The category IV toxic substance list.

The following substances are foreign toxic substances that the Secretary has determined are not found in any American workplace. They are:

Name:	*Federal Register date of final publication*
1. French water	Aug. 25, 1977

MODEL STANDARDS

§ 1990.150 Section 6(c) Model Standard for a Category I Toxic Substance.

OCCUPATIONAL EXPOSURE TO *XXXXX*

EMERGENCY TEMPORARY STANDARD

Section 1910.0000 *xxxx*

(a) *Scope and application.* This section applies to all occupational exposures to *xxxxx*, (Chemical Abstracts Service Registry Number *00000*), except that this section does not apply to: (*to be filled in as applicable.*)

(b) *Definitions.* "*xxxxx*" means (*definition of substance to be regulated*).

"Authorized person" means any person specifically authorized by the employer and whose duties require the person to be present in areas where *xxxxx* is present; and any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits.* (1) *Inhalation.* (i) *Time-weighted average limit (TWA).* Within (*insert appropriate time*) from the effective date of this emergency temporary standard, the employer shall assure that no employee is exposed to an airborne concentration of *xxxxx* in excess of: (*insert appropriate exposure limit representing the lowest feasible level that can be compiled with immediately*) as an eight (8)-hour time-weighted average.

(ii) *Ceiling limit.* (*If appropriate.*) The employer shall assure that no employee is exposed to an airborne concentration of *xxxxx* in excess of: (*insert appropriate exposure limit representing the lowest feasible level that can be complied with immediately*) as averaged over any: (*insert appropriate time period*) during the working day.

(2) *Dermal and eye exposure.* The employer shall assure that no employee is exposed to eye contact or skin contact with *xxxxx*.

(d) *Notification of Use.* Within (*insert appropriate time*) of the effective date of this section, or within fifteen (15) days following the introduction of *xxxxx* into the workplace, every employer shall report the following information to the nearest OSHA Area Office for each such workplace:

(1) The address and location of each workplace in which *xxxxx* is present;

(2) A brief description of each process or operation which may result in employee exposure to *xxxxx*;

(3) The number of employees engaged in each process or operation who may be exposed to *xxxxx* and an estimate of the frequency and degree of exposure that occurs; and

(4) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to *xxxxx*;

(e) *Exposure monitoring.* (1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to *xxxxx* over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial monitoring.* Each employer who has a place of employment in which *xxxxx* is present shall monitor, within thirty (30) days of the effective date of this standard, each such workplace and work operation to accurately determine the airborne concentrations of *xxxxx* to which employees may be exposed.

(3) *Frequency.*

(i) If the monitoring, required by this section, reveals employee exposure to be below the permissible exposure limits, the employer shall repeat such monitoring at least quarterly.

(ii) If the monitoring, required by this section, reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat these determinations for each such employee at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) *Additional monitoring.* Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to *xxxxx*, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to *xxxxx*, additional monitoring which complies with this paragraph shall be conducted.

(5) *Employee notification.*

(i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) *Accuracy of measurement.* The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus (*insert appropriate value*) for concentrations of *xxxxx* at or above the permissible exposure limits.

(7) *Type of monitoring.* (*Where applicable, specific mandatory monitoring, devices and techniques may be required.*)

(f) *Regulated areas.* (Deleted.)

(g) *Methods of compliance.* (1) *General policy.* OSHA's general policy as to methods of compliance for permanent standards has traditionally required that employee exposures to a substance be reduced to the permissible exposure limits solely by use of engineering and work practice controls. OSHA has permitted reduction of employee exposures by use of respiratory protection only where the employer proves that engineering and work practice controls are not feasible to reduce such exposures to the permissible exposure limits. This general policy is inherent in the model standards found in 29 CFR 1990.160 and 1990.170. However, during the effective period of this emergency temporary standard, OSHA recognizes the need to permit employee exposures to airborne concentrations of *xxxxx* to be controlled by any practicable combination of engineering controls, work practices and personal protective devices and equipment as follows. OSHA recognizes that the immediate reduction of exposure to *xxxxx* may generally be achieved primarily through the use of respiratory protection and the institution of good work practices during the effective period of this emergency temporary standard, such as the prohibitions against the blowing of dust containing *xxxxx* or the permitting of open containers and vessels of liquids containing *xxxxx*. On the other hand, OSHA believes that where engineering or work practice controls can reduce exposure, they should be used, even where such controls by themselves do not reduce the exposures to the permissible exposure limits. Thus, engineering controls to reduce the airborne concentration of *xxxxx* shall be instituted, if practicable, as soon as possible. Examples of such controls include substitution of a less hazardous material, enclosure of the process, and use of local exhaust ventilation systems. The employer should also examine each work area in which *xxxxx* is present and institute, as soon as possible, work practices to reduce employee exposures to *xxxxx* to or below the permissible exposure limits. Examples of such work practices include, among other things, limiting access to work areas where *xxxxx* is present to authorized personnel only; written procedures and work practices for each operation which may result in employee exposure to *xxxxx*; prohibiting smoking and the consumption of food and beverages in work areas where *xxxxx* is present; requiring the use of appropriate personal protective clothing and equipment to minimize eye and skin contact with *xxxxx*; use of signs, labels, or other means to clearly designate all work areas where *xxxxx* may be present; and institution of good housekeeping practices as set forth in paragraph (k) of this section. Finally, as pointed out, when-

ever the engineering and work practice controls described are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer should supplement them by the use of respiratory protection which complies with the requirements of the emergency temporary standard.

(2) *Engineering and work practice control plan.* (i) Within ninety (90) days of the effective date of this emergency temporary standard, the employer shall develop a written plan describing proposed means to reduce employee exposures to the lowest feasible level solely by means of engineering and work practice controls (which will be eventually required by a permanent standard for occupational exposure to *xxxxx*, issued pursuant to section 1990.160(g) of this subpart).

(ii) Written plans required by this paragraph shall be submitted, upon request, to the Assistant Secretary and the Director and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or designated representative.

(h) *Respiratory protection.* (1) *Required use.* The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposures to within the permissible exposure limits and in emergencies.

(2) *Respirator selection* (i) Where respiratory protection is required or permitted under this section, the employer shall select and provide at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee wears the respirator provided.

TABLE 1

RESPIRATORY PROTECTION FOR XXXXX

* * * * *

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to *xxxxx*.)

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e) and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator face piece to prevent potential skin irritation associated with respirator use.

(i) *Emergency situations.* (Deleted.)

(j) *Protective clothing and equipment.*

(1) *Provision and use.* Where eye or skin contact with *xxxxx* may occur, the employer shall provide, at no cost to the employee, and assure that employees wear, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and .133 to protect the area of the body which may come in contact with *xxxxx*.

(2) *Cleaning and replacement.*

(i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph, as needed, to maintain their effectiveness. In addition the employer shall provide clean protective clothing and equipment at least (*insert appropriate time*) to each affected employee.

(ii) The employer shall assure that the employee removes all protective clothing and equipment at the completion of a workshift.

(iii) The employer shall assure that *xxxxx*-contaminated protective clothing and equipment is placed and stored in closed containers which prevent dispersion of *xxxxx* outside the container.

(iv) The employer shall inform any person who launders or cleans *xxxxx* contaminated protective clothing or equipment of the potentially harmful effects of exposure to *xxxxx*.

(v) The employer shall assure that the containers of contaminated protective clothing and equipment which are to be removed from the workplace for any reason are labeled in accordance with paragraph (p)(3) of this section.

(vi) The employer shall prohibit the removal of *xxxxx* from protective clothing or equipment by blowing or shaking.

(k) *Housekeeping.* (1) *Surfaces.* (i) All surfaces shall be maintained free of accumulations of *xxxxx*.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces where *xxxxx* dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either portable units or a permanent system may be used.

(A) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that *xxxxx* is not reintroduced into the work place air; and

(B) Portable vacuum units used to collect *xxxxx*, may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (p)(3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) *Liquids.* Where *xxxxx* is present in a liquid form, or as a resultant vapor, all containers or vessels containing *xxxxx* shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(l) *Waste disposal. xxxxx* waste, scrap, debris, bags, containers, or equipment shall be disposed of in sealed bags or other closed containers which prevent dispersion of *xxxxx* outside the container.

(m) *Hygiene facilities and practices.* Where employees are exposed to airborne concentrations of *xxxxx*, or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the facilities required by 29 CFR 1910.141 shall be provided by the employer for the use of those employees, and the employer shall assure that the employees use the facilities provided.

(n) *Medical surveillance.* (1) *General.* (i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to *xxxxx*. The employee shall provide each such employer with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) *Initial examinations.* Within thirty (30) days of the effective date of this section, or thereafter at the time of initial assignment, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history, a medical history, and a physical examination with direct emphasis towards the pulmonary, renal, and hepatic systems, and shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors. Additionally, such factors as the current systems review, pregnancy, current treatment with steroids or cytotoxic agents, and smoking habits should be considered.

(ii) The medical examination shall also include the following: (*insert appropriate medical protocol*).

(3) *Periodic examinations.* (*Insert appropriate medical protocol and time.*)

(4) *Interim examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to *xxxxx*, the employer shall provide appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this emergency temporary standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level; and

(iv) A description of any personal protective equipment used or to be used.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to *xxxxx*;

(C) Any recommended limitations upon the employee's exposure to *xxxxx* or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to *xxxxx*;

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee information and training.* (1) *Training program.* (i) Within thirty (30) days from the effective date of this standard, the employer shall institute a training program for all employees where there is occupational exposure to *xxxxx* and shall assure their participation in the training program.

(ii) The employer shall assure that each employee is informed of the following:

(A) The information contained in Appendices A, B, and C;

(B) The quantity, location, manner of use, release, or storage of *xxxxx* and the specific nature of operations which could result in exposure to *xxxxx*, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators;

(D) The purpose and description of the medical surveillance program required by paragraph (n) of this section; and

(E) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) *Signs and labels.* (1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from such effects of the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all workplaces where *xxxxx* may be present. The signs shall bear the following legend:

DANGER

XXXXX

(*Insert appropriate trade or common names*)

CANCER HAZARD

AUTHORIZED PERSONS ONLY

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Where airborne concentrations of *xxxxx* exceed the permissible exposure limits, the signs shall bear the additional legend: "Respirators Required."

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of *xxxxx* and of products containing *xxxxx*, and that the labels remain affixed when the *xxxxx* or products containing *xxxxx* are sold, distributed, or otherwise leave the employer's workplace.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS *XXXXX*

CANCER HAZARD

(q) *Recordkeeping.* (1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for the effective period of this emergency temporary standard, and for any additional period required by the permanent standard.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions;

(B) Any employee medical complaints related to exposure to *xxxxx*;

(C) A copy of the information provided to the physician as required by paragraph (n)(6) of this section; and

(D) A copy of the employee's work history.

(iii) The employer shall assure that this record be maintained for the effective period of this emergency temporary standard, and for any additional period required by the permanent standard.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records, as required by this section, be made available, upon request, for examination and copying to the affected employee, former employee, or designated representative.

(iii) The employer shall assure that employee medical records required to be maintained by this section, be made available, upon request, for examination and copying to the affected employee or former employee, or to a physician designated by the affected employee, former employee, or designated representative.

(r) *Observation of monitoring.* (1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to *xxxxx* conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to *xxxxx* requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of *xxxxx* performed at the place of exposure; and

(C) Record the results obtained.

(s) *Effective date.* This section shall become effective (*insert date of publication*).

(t) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

APPENDIX A

SUBSTANCE SAFETY DATA SHEET

XXXXX

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES

XXXXX

APPENDIX C

MEDICAL SURVEILLANCE GUIDELINES

XXXXX

§ 1990.160 Section 6(b) Model Standard for a Category I Toxic Substance.

Occupational Exposure to *xxxxx*

Notice of Proposed or Final Rulemaking

§ 1910.0000 *xxxxx.*

(a) *Scope and application.* This section applies to all occupational exposures to *xxxxx* (Chemical Abstracts Service Registry Number *00000*), except that this section does not apply to: (*to be filled in as applicable*).

(b) *Definitions.* "*xxxxx*" means (*definition of substance to be regulated*).

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which is likely to, or does, result in unexpected exposure of *xxxxx* in excess of the ceiling limit.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits.* (1) *Inhalation.* (i) *Time-weighted average limit (TWA).* The employer shall assure that no employee is exposed to an airborne concentration of *xxxxx* in excess of: (*insert appropriate exposure limit representing: (a) the lowest feasible level, except as modified by paragraph (c)(3) of this section or (b) when it is determined by the Secretary that there are available substitutes for all uses or classes of uses that are less hazardous to humans, the proposal shall permit no occupational exposure*) as an eight (8) hour time-weighted average.

(ii) *Ceiling limit.* (*If appropriate.*) The employer shall assure that no employee is exposed to an airborne concentration of *xxxx* in excess of: (*insert appropriate exposure limit representing the lowest feasible level, which shall however, not be more than five (5) times the TWA*) as averaged over any: (*insert apporpriate time period*) during the working day.

(2) *Dermal and eye exposure.* The employer shall assure that no employee is exposed to eye contact or skin contact with *xxxxx.*

(3) *Other restrictions.* The employer shall assure that there is no occupational exposure to *xxxxx* from the following uses or classes of uses: (*Where the Secretary determines, in the proposal or upon the record of the public rulemaking, that there are materials less hazardous to employees and that those materials are suitable substitutes in certain applications where* xxxxx *might otherwise be used, the Secretary here shall specify that no occupational exposure to* xxxxx *be permitted* in those circumstances and uses, listing those *circumstances or uses.*).

(d) *Notification of use and emergencies.* (1) *Use.* Within (*insert appropriate time*), or within fifteen (15) days following the introduction of *xxxxx* into the workplace, every employer shall report, unless he has done so pursuant the emergency temporary standard issued pursuant to 29 CFR 1990.150(d) herein, the following information to the OSHA Area Office for each such workplace:

(i) The address and location of each workplace in which *xxxxx* is present;

(ii) A brief description of each process or operation which may result in employee exposure to *xxxxx;*

(iii) The number of employees engaged in each process or operation who may be exposed to *xxxxx* and an estimate of the frequency and degree of exposure that occurs;

(iv) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to *xxxxx;* and

(v) Whenever there has been a significant change in the information required by this paragraph or 29 CFR 1990.150(d), the employer shall promptly amend such information previously provided to the OSHA area office.

(2) *Emergencies and remedial action.* Emergencies, and the facts obtainable at that time, shall be reported within twenty-four (24) hours of the initial occurrence to the OSHA Area Office. Upon request of the OSHA Area Office, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of a similar nature.

(e) *Exposure monitoring.* (1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to *xxxxx* over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial monitoring.* Each employer who has a place of employment in which *xxxxx* is present shall monitor each such workplace and work operation to accurately determine the airborne concentrations of *xxxxx* to which employees may be exposed.

(3) *Frequency.* (i) If the monitoring, required by this section, reveals employee exposure to be below the permissible exposure limits, the employer shall repeat such monitoring at least quarterly.

(ii) If the monitoring, required by this section, reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat these determinations for each such employee at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) *Additional monitoring.* Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to *xxxxx*, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to *xxxxx*, additional monitoring which complies with this paragraph shall be conducted.

(5) *Employee notification.* (i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) *Accuracy of measurement.* The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus (*insert appropriate value*) for concentrations of *xxxxx* at or above the permissible exposure limits.

(7) *Type of monitoring.* (*Where applicable, specific mandatory monitoring devices and techniques may be required.*)

(f) *Regulated areas.* (1) The employer shall establish regulated areas where *xxxxx* concentrations are in excess of the permissible exposure limits.

(2) Regulated areas shall be demarcated and segregated from the rest of the workplace, in any manner that minimizes the number of persons who will be exposed to *xxxxx*.

(3) Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the Act or regulations issued pursuant thereto.

(4) The employer shall assure that in the regulated area, food or beverages are not present or consumed, smoking products are not present or used, and cosmetics are not applied (except that these activities may be conducted in the lunchroom, change rooms and showers required under paragraphs (m)(1)–(m)(3) of this section.)

(g) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) The employer shall institute engineering or work practice controls to reduce and maintain employee exposures to *xxxxx* to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (h) of this section.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits solely by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to *xxxxx*;

(B) Engineering plans and other studies used to determine the controls for each process;

(C) A report of the technology considered in meeting the permissible exposure limits;

(D) A detailed schedule for the implementation of engineering or work practice controls; and

(E) Other relevant information.

(iii) Written plans for such a program shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or representative.

(iv) The plans required by this paragraph shall be revised and updated at least every six (6) months to reflect the current status of the program.

(h) *Respiratory protection.* (1) *General.* The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposures to within the permissible exposure limits and in emergencies. Compliance with the permissible exposure limits may not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement feasible engineering and work practice controls; or

(ii) In work operations such as maintenance and repair activities in which the employer establishes that engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide at no cost to the employee, the appropriate type of respirator from Table 1 below and shall assure that the employee wears the respirator provided.

TABLE 1

RESPIRATORY PROTECTION FOR XXXXX

* * * * *

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to *xxxxx*).

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator facepiece to prevent potential skin irritation associated with respirator use.

(i) *Emergency situations.* (1) *Written plans.* (i) A written plan for emergency situations shall be developed for each workplace where *xxxxx* is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraph (h) of this section until the emergency is abated.

(2) *Alerting employees.* (i) *Alarms.* Where there is the possibility of employee exposure to *xxxxx* in excess of the ceiling limit due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(ii) *Evacuation.* Employees not engaged in correcting the emergency shall be restricted from the area and shall not be permitted to return until the emergency is abated.

(j) *Protective clothing and equipment.* (1) *Provision and use.* Where eye or skin contact with *xxxxx* may occur, the employer shall provide at no cost to employee, and assure that employees wear, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and .133 to protect the area of the body which may come in contact with *xxxxx*.

(2) *Cleaning and replacement.* (i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph, as needed, to maintain their effectiveness. In addition, the employer shall provide clean protective clothing and equipment at least (*insert appropriate time*) to each affected employee.

(ii) The employer shall assure that the employee removes all protective clothing and equipment at the completion of a work shift and only in change rooms as required by paragraph (m)(1) of this section.

(iii) The employer shall assure that *xxxxx*-contaminated protective clothing and equipment is placed and stored in closed containers which prevent dispersion of *xxxxx* outside the container.

(iv) The employer shall assure that no employee removes *xxxxx*-contaminated protective equipment or clothing from the change room, except for those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(v) The employer shall inform any person who launders or cleans *xxxxx* contaminated protective clothing or equipment of the potentially harmful effects of exposure to *xxxxx*.

(vi) The employer shall assure that the containers of contaminated protective clothing and equipment which are to be removed from the workplace for any reason are labeled in accordance with paragraph (p)(3)(ii) of this section.

(viii) The employer shall prohibit the removal of *xxxxx* from protective clothing or equipment by blowing or shaking.

(k) *Housekeeping.* (1) *Surfaces.* (i) All surfaces shall be maintained free of accumulations of *xxxxx*.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces where *xxxxx* dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either protable units or a permanent system may be used.

(A) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that *xxxxx* is not reintroduced into the work place air; and

(B) Portable vacuum units used to collect *xxxxx*, may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (p)(3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) *Liquids.* Where *xxxxx* is present in a liquid form, or as a resultant vapor, all containers or vessels containing *xxxxx* shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) *Dust collection systems.* Periodic cleaning of dust collection systems; i.e., ducts and filters, shall be performed to reduce *xxxxx* dust buildups and to maintain the effectiveness of the system.

(l) *Waste disposal, xxxxx* waste, scrap, debris, bags, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of *xxxxx* outside the container.

(m) *Hygiene facilities and practices.* Where employees are exposed to airborne concentrations of *xxxxx*, or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the facilities required by 29 CFR 1910.141 shall be provided by the employer for the use of those employees and the employer shall assure that the employees use the facilities provided. In addition, the following additional facilities or requirements are mandated.

(1) *Change rooms.* The employer shall provide clean change rooms in accordance with 29 CFR 1910.141(e).

(2) *Showers.* (i) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(ii) In addition, the employer shall also assure that employees exposed to *xxxxx* shower at the end of the work shift.

(3) *Lunchrooms.* (i) Whenever food or beverages are consumed in the workplace, the employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees exposed to *xxxxx*.

(ii) In addition the employer shall also assure that employees exposed to *xxxxx* wash their hands and face prior to eating.

(n) *Medical Surveillance.* (1) *General.* (i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to *xxxxx*. The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervison of a licensed physician, and shall be provided without cost to the employee.

(2) *Initial examinations.* At the time of initial assignment, or upon institution of the medical surveillance program, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history, a medical history, and a physical examination with direct emphasis towards the pulmonary, renal and hepatic systems, and shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors. Additionally, such factors as the current systems review, pregnancy, current treatment with steroids or cytotoxic agents, and smoking habits should be considered.

(ii) The medical examination shall also include the following: (*insert appropriate medical protocol*).

(3) *Periodic examinations.* (i) The employer shall provide examinations specified in this paragraph at least (*insert appropriate time*) for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examinations prescribed in paragraph (n)(2) of this section within 6 months of termination of employment, the employer shall make such examination available to the employee upon such termination.

(4) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to *xxxxx*, the employer shall provide appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) Information from previous medical examinations of the affected employee, which is not otherwise available to the examining physician.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to *xxxxx*;

(C) Any recommended limitations upon the employee's exposure to *xxxxx* or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to *xxxxx*;

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee Information and Training.* (1) *Training Program.* (i) The employer shall institute a training program for all employees where there is occupational exposure to *xxxxx* and shall assure their participation in the training program.

(ii) The training program shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter, and the employer shall assure that each employee is informed of the following:

(A) The information contained in Appendices A, B and C;

(B) The quantity, location, manner of use, release or storage of *xxxxx* and the specific nature of operations which could result in exposure to *xxxxx*, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of the respirators;

(D) The purpose and a description of the medical surveillance program required by paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section; and

(F) The engineering and work practice controls, their function and the employee's relationship thereto; and

(G) A review of this standard.

(2) *Access to Training Materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) *Signs and Labels.* (1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from such effects of the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all workplaces where *xxxxx* may be present. The signs shall bear the following legend:

DANGER

XXXXX

(*insert appropriate trade or common names*)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Where airborne concentrations of *xxxxx* exceed the permissible exposure limits, the signs shall bear the additional legend: "Respirator Required"

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of *xxxxx* and of products containing *xxxxx*, and that the labels remain affixed when the *xxxxx* or products containing *xxxxx* are sold, distributed or otherwise leave the employer's workplace.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS *XXXXX*

CANCER HAZARD

(q) *Recordkeeping.* (1) *Exposure Monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) *Medical Surveillance.* (i) The employer shall establish and maintain an accurate

record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions;

(B) Any employee medical complaints related to exposure to *xxxxx;*

(C) A copy of the information provided to the physician as required by paragraph (n) (6) of this section; and

(D) A copy of the employee's work history.

(iii) The employer shall assure that this record be maintained for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records, as required by this section, be made available, upon request, for examination and copying to the affected employee, former employee, or designated representative.

(iii) The employer shall assure that employee medical records required to be maintained by this section, be made available, upon request, for examination and copying, to the affected employee or former employee, or to a physician designated by the affected employee, former employee, or designated representative.

(4) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained pursuant to this section, the employer shall transmit these records to the Director.

(r) *Observation of Monitoring.* (1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to *xxxxx* conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to *xxxxx* requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of *xxxxx* performed at the place of exposure; and

(C) Record the results obtained.

(s) *Effective date.* This section shall become effective (*insert appropriate period*) following publication.

(t) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

APPENDIX A

SUBSTANCE SAFETY DATA SHEET

XXXXX

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES

XXXXX

APPENDIX C

MEDICAL SURVEILLANCE GUIDELINES

XXXXX

§ 1990.170 Section 6(b) Model Standard for a Category II Toxic Substance.

OCCUPATIONAL EXPOSURE TO XXXXX

NOTICE OF PROPOSED OR FINAL RULEMAKING

§ 1910.0000 *xxxxx.*

(a) *Scope and application.* This section applies to all occupational exposures to *xxxxx* (Chemical Abstracts Service Registry Number *00000*), except that this section does not apply to: (*to be filled in as applicable.*)

(b) *Definitions.* "*xxxxx*" means (*definition of substance to be regulated*).

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which is likely to, or does, result in unexpected exposure, of *xxxxx* in excess of the ceiling limit.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits.* (1) *Inhalation.* (i) *Time-weighted average limit (TWA).* The employer shall assure that no employee is exposed to an airborne concentration of *xxxxx* in excess of: (*insert appropriate exposure limit representing* (a) *the present OSHA standard found in 29 CFR 1910.1000 or* (b) *where none exists, an appropriate level based upon acute or chronic effects of exposure to xxxxx other than carcinogenicity or* (c) *where acute or chronic effects other than carcinogenicity indicate that the present OSHA standard is inadequate, the exposure level shall be lowered from the present OSHA standard to the level found appropriate by the Secretary to protect against such effects*) as an eight (8)-hour time-weighted average.

(ii) *Ceiling limit.* (*If appropriate.*) The employer shall assure that no employee is exposed to an airborne concentration of *xxxxx* in excess of: (*insert the appropriate exposure limit*) as averaged over any: (*insert appropriate time period*) during the working day.

(2) *Dermal and eye exposure.* The employer shall assure that no employee is exposed to eye contact or skin contact with *xxxxx.*

(d) *Notification of use and emergencies.* (1) *Use.* Within (*insert appropriate time*), or within fifteen (15) days the introduction of *xxxxx* into the workplace, every employer shall report the following information to the OSHA Area Office for each such workplace:

(i) The address and location of each workplace in which *xxxxx* is present;

(ii) A brief description of each process or operation, which may result in employee exposure to *xxxxx;*

(iii) The number of employees engaged in each process or operation who may be exposed to *xxxxx* and an estimate of the frequency and degree of exposure that occurs;

(iv) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to *xxxxx;* and

(v) Whenever there has been a significant change in the information required by this paragraph, the employer shall promptly amend such information previously provided to the OSHA area office.

(2) *Emergencies and Remedial Action.* Emergencies, and the facts obtainable at that time, shall be reported within twenty-four (24) hours of the initial occurence to the OSHA Area Office. Upon request of the OSHA Area Office, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of a similar nature.

(e) *Exposure monitoring.* (1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to *xxxxx* over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial monitoring.* Each employer who has a place of employment in which *xxxxx* is present shall monitor each such workplace and work operation to accurately determine the airborne concentration of *xxxxx* to which employees may be exposed.

(3) *Frequency.* (i) If the monitoring, required by this section, reveals employee exposure to be below the permissible exposure limits, the employer shall repeat such monitoring at least quarterly.

(ii) If the monitoring, required by this section, reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat the determinations for each such employees at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) *Additional monitoring.* Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to *xxxxx,* or whenever the employer has any other reason to suspect a change which may result in new or additional exposure to *xxxxx,* additional monitoring which complies with this paragraph shall be conducted.

(5) *Employee notification.* (i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever such results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice

a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) *Accuracy of measurement.* The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus (*insert appropriate value*) for concentrations of *xxxxx* at or above the permissible exposure limit.

(7) *Type of monitoring.* (*Where applicable, specific mandatory monitoring and techniques may be required.*)

(f) *Regulated areas.* (Deleted.)

(g) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) The employer shall institute engineering or work practice controls to reduce and maintain employee exposures to *xxxxx* to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest levels achievable by those controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (h) of this section.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits solely by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to *xxxxx;*

(B) Engineering plans and other studies used to determine the controls for each process;

(C) A report of the technology considered in meeting the permissible exposure limits;

(D) A detailed schedule for the implementation of engineering or work practice controls; and

(E) Other relevant information.

(iii) Written plans for such a program shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or representative.

(iv) The plans required by this paragraph shall be revised and updated at least every six (6) months to reflect the current status of the program.

(h) *Respiratory protection.* (1) *General.* The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposure to within the permissible exposure limits and in emergencies. Compliance with the permissible exposure limits may not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement feasible engineering and work practice controls; or

(ii) In work operations such as maintenance and repair activities in which the employer establishes that engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide at no cost to the employee, the appropriate type of respirator from Table 1 below and shall assure that the employee uses the respirator provided.

TABLE 1

RESPIRATORY PROTECTION FOR *xxxxx*

* * * * *

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to *xxxxx*).

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator facepiece to prevent potential skin irritation associated with respirator use.

(i) *Emergency situations.* (1) *Written plans.* (i) A written plan for emergency situations shall be developed for each workplace where *xxxxx* is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraph (h) of this section until the emergency is abated.

(2) *Alerting employees.* (i) *Alarms.* Where there is the possibility of employee exposure to *xxxxx* in excess of the ceiling limit due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(ii) *Evacuation.* Employees not engaged in correcting the emergency shall be restricted from the area and shall not be permitted to return until the emergency is abated.

(j) *Protective clothing and equipment.* (1) *Provision and use.* Where eye or skin contact with *xxxxx* may occur, the employer shall provide at no cost to the employee, and assure that employees wear, appropriate protective clothing or equipment in accordance with 29 CFR 1910.132 and .133 to protect the area of the body which may come in contact with *xxxxx.*

(2) *Cleaning and replacement.* (i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph, as needed, to maintain their effectiveness. In addition the employer shall provide clean protective clothing and equipment at least (*insert appropriate time*) to each affected employee.

(ii) The employer shall assure that the employee removes all protective clothing and equipment at the completion of a work shift and only in change roms as required by paragraph (m)(1) of this section.

(iii) The employer shall assure that *xxxxx*-contaminated protective clothing and equipment is placed and stored in closed containers which prevent dispersion of *xxxxx* outside the container.

(iv) The employer shall assure that no employee removes contaminated protective equipment or clothing from the change room except for those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(v) The employer shall inform any person who launders or cleans *xxxxx* contaminated protective clothing or equipment of the potentially harmful effects of exposure to *xxxxx.*

(vi) The employer shall assure that the containers of contaminated protective clothing and equipment which are to be removed from the workplace for any reason are labeled in accordance with paragraph (p)(3)(ii) of this section.

(vii) The employer shall prohibit the removal of *xxxxx* from protective clothing or equipment by blowing or shaking of work clothing.

(k) *Housekeeping.* (1) *Surfaces.* (i) All surfaces shall be maintained free of accumulations of *xxxxx.*

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces where *xxxxx* dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either portable units or a permanent system may be used.

(A) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters, or other appropriate means of contaminant removal, so that *xxxxx* is not reintroduced into the work place air; and

(B) Portable vacuum units used to collect *xxxxx*, may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (p)(3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) *Liquids.* Where *xxxxx* is present in a liquid form, or as a resultant vapor, all containers or vessels containing *xxxxx* shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) *Dust collection systems.* Periodic cleaning of dust collection systems, i.e. ducts and filters, shall be performed to reduce *xxxxx* dust buildups and to maintain the effectiveness of the system.

(l) *Waste disposal. xxxxx* waste, scrap, debris, bags, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of *xxxxx* outside the container.

(m) *Hygiene facilities and practices.* Where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the facilities required by 29 CFR 1910.141 or in this paragraph shall be provided by the employer for the use of those employees and the employer shall assure that the employees use the facilities provided. In addition, the following additional facilities or requirements are mandated.

(1) *Change rooms.* The employer shall provide clean change rooms in accordance with 29 CFR 1910.141(e).

(2) *Showers.* (i) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(ii) In addition, the employer shall also assure that employees exposed to *xxxxx* shower at the end of the work shift.

(3) *Lunchrooms.* (i) The employer shall provide appropriate facilities for eating and drinking in accordance with 29 CFR 1910.141 (g) and (h).

(ii) The employer shall assure that employees exposed to *xxxxx* wash their hands and face prior to eating.

(n) *Medical Surveillance.* (1) *General.* (i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to *xxxxx.* The employer shall provide each employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a

licensed physician, and shall be provided without cost to the employee.

(2) *Initial examinations.* At the time of initial assignment, or upon institution of the medical surveillance program, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements.

(i) A work history, a medical history, and a physical examination with direct emphasis towards the pulmonary, renal and hepatic systems, and shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors. Additionally, such factors as the current systems review, pregnancy, current treatment with steroids or cytotoxic agents, and smoking habits should be considered.

(ii) The medical examination shall also include the following: (*insert appropriate medical protocol*).

(3) *Periodic examinations.* (i) The employer shall provide examinations specified in this paragraph at least (*insert appropriate time*) for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examinations prescribed in paragraph (n)(2) of this section within 6 months of termination of employment, the employer shall make such examination available to the employee upon such termination.

(4) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to *xxxxx*, the employer shall provide appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure,

(iii) The employee's representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) Information from previous medical examinations of the affected employee, which is not otherwise available to the examining physician.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to *xxxxx*;

(C) Any recommended limitations upon the employee's exposure to *xxxxx* or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to *xxxxx*.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee information and training.* (1) *Training program.* (i) The employer shall institute a training program for all employees where there is occupational exposure to *xxxxx* and shall assure their participation in the training program.

(ii) The training program shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter, and the employer shall assure that each employee is informed of the following:

(A) The information contained in Appendices A, B, and C;

(B) The quantity, location, manner of use, release or storage of *xxxxx* and the specific nature of operations which could result in exposure to *xxxxx*, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators;

(D) The purpose and a description of the medical surveillance program required by paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section;

(F) The engineering and work practice controls, their function and the employee's relationship thereto; and

(G) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) *Signs and labels.* (1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from the effects of such required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all work areas where *xxxxx* may be present. The signs shall bear the following legend:

CAUTION

XXXXX

(*insert appropriate trade or common names*)

POTENTIAL CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readibly visible.

(iii) Where airborne concentrations of *xxxxx* exceed the permissible exposure limits, the signs shall bear the additional legend:

RESPIRATOR REQUIRED

(3) *Labels.* The employer shall assure that precautionary labels are affixed to all containers of *xxxxx* and of products containing *xxxxx* and that the labels remain affixed when the *xxxxx* or products containing *xxxxx* are sold, distributed or otherwise leave the employer's workplace. The label shall bear the following legend:

CAUTION

CONTAINS *XXXXX*

POTENTIAL CANCER HAZARD

(q) *Recordkeeping.* (1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions;

(B) Any employee medical complaints related to exposure to *xxxxx;*

(C) A copy of the information provided to the physician as required by paragraph (n)(6) of this section; and

(D) A copy of the employee's work history.

(iii) The employer shall assure that this record be maintained for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records, as required by this section, be made available, upon request, for examination and copying, to the affected employee, former employee, or designated representative.

(iii) The employer shall assure that employee medical records required to be maintained by this section, be made available, upon request, for examination and copying to the affected employee or former employee, or to a physician designated by the affected employee, former employee, or designated representative.

(4) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained pursuant to this section, the employer shall transmit these records to the Director.

(r) *Observation of monitoring.* (1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to *xxxxx* conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to *xxxxx* requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of *xxxxx* performed at the place of exposure; and

(C) Record the results obtained.

(s) *Effective dates.* This section shall become effective (*insert appropriate period*) following publication.

(t) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligations.

APPENDIX A

SUBSTANCE SAFETY DATA SHEET

XXXXX

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES

XXXXX

APPENDIX C

MEDICAL SURVEILLANCE GUIDELINES

XXXXX

Subpart C—Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Teratogenic Risk [Reserved]

(Secs. 4, 6, 8, 84 Stat. 1593, 1599 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8–76 (41 FR 25059); 29 FR Part 1911.)

MODEL STANDARDS

Section 1990.150. Section 6(c) Model Standard for a Category I Toxic Substance

Emergency Temporary Standard

Section 1910.0000 xxxxx

(a) Scope and application. This section applies to all occupational exposures to xxxxx, (Chemical Abstracts Service Registry Number (0000), except that this section does not apply to: (to be filled in as applicable.)

Section 1990.160. Section 6(b) Model Standard for a Category I Toxic Substance

Notice of Proposed or Final Rulemaking

Section 1910.0000 xxxxx

(a) Scope and application. This section applies to all occupational exposures to xxxxx, (Chemical Abstracts Service Registry Number (0000), except that this section does not apply to: (to be filled in as applicable.)

Section 1990.170. Section 6(b) Model Standard for a Category II Toxic Substance

Notice of Proposed or Final Rulemaking

Section 1910.0000 xxxxx

(a) Scope and application. This section applies to all occupational exposures to xxxxx (Chemical Abstracts Service Registry Number (0000), except that this section does not apply to: (to be filled in as applicable.)

(b) Definitions.

"xxxxx" means (definition of substance to be regulated).

"Authorized person" means any person specifically authorized by the employer and whose duties require the person to be a present in areas where xxxxx is present; and any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education and Welfare, or designee.

(b) Definitions.

"xxxxx" means (definition of substance to be regulated).

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U. S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U. S. Department of Health, Education and Welfare, or designee.

(b) Definitions.

"xxxxx" means (definition of substance to be regulated).

" Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U. S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U. S. Department of Health, Education and Welfare, or designee.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which is likely to, or does, result in unexpected exposure of xxxxx in excess of the ceiling limit.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which is likely to, or does, result in unexpected exposure, of xxxxx in excess of the ceiling limit.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) Permissible exposure limits.

(1) Inhalation.

(i) Time-weighted average limit (TWA). Within (insert appropriate time) from the effective date of this emergency temporary standard, the employer shall assure that no employee is exposed to an airborne concentration of xxxxx in excess of: (insert appropriate exposure limit representing the lowest feasible level that can be complied with immediately) as an eight (8)-hour time-weighted average.

(c) Permissible exposure limits.

(1) Inhalation.

(i) Time-weighted average limit (TWA). The employer shall assure that no employee is exposed to an airborne concentration of xxxxx in excess of: (insert appropriate exposure limit representing: (a) the lowest feasible level, except as modified by paragraph (c)(3) of this section or (b) when it is determined by the Secretary that there are available substitutes for all uses or classes of uses that are less hazardous to humans, the proposal shall permit no occupational exposure) as an eight (8)-hour time-weighted average.

(c) Permissible exposure limits.

(1) Inhalation.

(i) Time-weighted average limit (TWA). The employer shall assure that no employee is exposed to an airborne concentration of xxxxx in excess of: (insert appropriate exposure limit representing (a) the present OSHA standard found in 29 CFR 1910.1000 or (b) where none exists, an appropriate level based upon acute or chronic effects of exposure to xxxxx other than carcinogenicity or (c) where acute or chronic effects other than carcinogenicity indicate that the present OSHA standard is inadequate, the exposure level shall be lowered from the present OSHA standard to the level found appropriate by the Secretary to protect against such effects) as an eight (8)-hour time-weighted average.

(ii) Ceiling limit. (If appropriate.) The employer shall assure that no employee is exposed to an airborne concentration of xxxxx in excess of: (insert appropriate exposure limit representing the lowest feasible level that can be complied with immediately) as averaged over any: (insert appropriate time period) during the working day.

(2) Dermal and eye exposure. The employer shall assure that no employee is exposed to eye contact or skin contact with xxxxx.

(ii) Ceiling limit. (If appropriate.) The employer shall assure that no employee is exposed to an airborne concentration of xxxxx in excess of: (insert appropriate exposure limit representing the lowest feasible level, which shall however, not be more than five (5) times the TWA) as averaged over any: (insert appropriate time period) during the working day.

(2) Dermal and eye exposure. The employer shall assure that no employee is exposed to eye contact or skin contact with xxxxx.

(3) Other restrictions. The employer shall assure that there is no occupational exposure to xxxxx from the following uses or classes of uses: (Where the Secretary determines, in the proposal or upon the record of the public rulemaking, that there are materials less hazardous to employees and that those materials are suitable substitutes in certain applications

(ii) Ceiling limit. (If appropriate.) The employer shall assure that no employee is exposed to an airborne concentration of xxxxx in excess of: (insert the appropriate exposure limit) as averaged over any: (insert appropriate time period) during the working day.

(2) Dermal and eye exposure. The employer shall assure that no employee is exposed to eye contact or skin contact with xxxxx.

where xxxxx might otherwise be used, the Secretary here shall specify that no occupational exposure to xxxxx shall be permitted in those circumstances and uses, listing those circumstances or uses.)

(d) Notification of Use. Within (insert appropriate time) of the effective date of this section, or within fifteen (15) days following the introduction of xxxxx into the workplace, every employer shall report the following information to the nearest OSHA Area Office for each such workplace:

(1) The address and location of each workplace in which xxxxx is present;

(2) A brief description of each process or operation which may result in employee exposure to xxxxx;

(3) The number of employees engaged in each process or operation who may be exposed to xxxxx and an estimate of the frequency and degree of exposure that occurs; and

(d) Notification of use and emergencies.

(1) Use.

Within (insert appropriate time), or within fifteen (15) days following the introduction of xxxxx into the workplace, every employer shall report, unless he has done so pursuant the emergency temporary standard issued pursuant to 29 CFR 1990.150(d) herein, the following information to the OSHA Area Office for each such workplace:

(i) The address and location of each workplace in which xxxxx is present;

(ii) A brief description of each process or operation which may result in employee exposure to xxxxx;

(iii) The number of employees engaged in each process or operation who may be exposed to xxxxx and an estimate of the frequency and degree of exposure that occurs;

(d) Notification of use and emergencies.

(1) Use.

Within (insert appropriate time), or within fifteen (15) days the introduction of xxxxx into the workplace, every employer shall report the following information to the OSHA Area Office for each such workplace:

(i) The address and location of each workplace in which xxxxx is present;

(ii) A brief description of each process or operation, which may result in employee exposure to xxxxx;

(iii) The number of employees engaged in each process or operation who may be exposed to xxxxx and an estimate of the frequency and degree of exposure that occurs;

(4) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to xxxxx;

(iv) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to xxxxx; and

(v) Whenever there has been a significant change in the information required by this paragraph or 29 CFR 1990.150(d), the employer shall promptly amend such information previously provided to the OSHA area office.

(2) Emergencies and remedial action. Emergencies, and the facts obtainable at that time, shall be reported within twenty four (24) hours of the initial occurrence to the OSHA Area Office. Upon request of the OSHA Area Office, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of a similar nature.

(iv) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to xxxxx; and

(v) Whenever there has been a significant change in the information required by this paragraph, the employer shall promptly amend such information previously provided to the OSHA area office.

(2) Emergencies and Remedial Action. Emergencies, and the facts obtainable at that time, shall be reported within twenty-four (24) hours of the initial occurrence to the OSHA Area Office. Upon request of the OSHA Area Office, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of a similar nature.

(e) Exposure monitoring.

(1) General.

(i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to xxxxx over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) Initial monitoring. Each employer who has a place of employment in which xxxxx is present shall monitor, within thirty (30) days of the effective date of this standard, each such workplace and work operation to accurately determine the airborne concentrations of xxxxx to which employees may be exposed.

(e) Exposure monitoring.

(1) General.

(i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to xxxxx over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) Initial monitoring. Each employer who has a place of employment in which xxxxx is present shall monitor each such workplace and work operation to accurately determine the airborne concentrations of xxxxx to which employees may be exposed.

(e) Exposure monitoring.

(1) General.

(i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to xxxxx over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) Initial monitoring. Each employer who has a place of employment in which xxxxx is present shall monitor each such workplace and work operation to accurately determine the airborne concentrations of xxxxx to which employees may be exposed.

(3) Frequency.

(i) If the monitoring, required by this section, reveals employee exposure to be below the permissible exposure limits, the employer shall repeat such monitoring at least quarterly.

(ii) If the monitoring, required by this section, reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat these determinations for each such employees at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) Additional monitoring. Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to xxxxx, or whenever the

(3) Frequency.

(i) If the monitoring, required by this section, reveals employee exposure to be below the permissible exposure limits, the employer shall repeat such monitoring at least quarterly.

(ii) If the monitoring, required by this section, reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat these determinations for each such employee at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) Additional monitoring. Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to xxxxx, or whenever the

(3) Frequency.

(i) If the monitoring, required by this section, reveals employee exposure to be below the permissible exposure limits, the employer shall repeat such monitoring at least quarterly.

(ii) If the monitoring, required by this section, reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat the determinations for each such employees at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) Additional monitoring. Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to xxxxx, or whenever the

employer has any other reason to suspect a change which may result in new or additional exposures to xxxxx, additional monitoring which complies with this paragraph shall be conducted.

(5) Employee notification.

(i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

employer has any other reason to suspect a change which may result in new or additional exposures to xxxxx, additional monitoring which complies with this paragraph shall be conducted.

(5) Employee notification.

(i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employees exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

employer has any other reason to suspect a change which may result in new or additional exposure to xxxxx, additional monitoring which complies with this paragraph shall be conducted.

(5) Employee notification.

(i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever such results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) Accuracy of measurement. The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus (insert appropriate value) for concentrations of xxxxx at or above the permissible exposure limits.

(7) Type of monitoring. (Where applicable, specific mandatory monitoring devices and techniques may be required.)

(6) Accuracy of measurement. The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus (insert appropriate value) for concentrations of xxxxx at or above the permissible exposure limits.

(7) Type of monitoring. (Where applicable, specific mandatory monitoring devices and techniques may be required.)

(6) Accuracy of measurement. The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus (insert appropriate value) for concentrations of xxxxx at or above the permissible exposure limit.

(7) Type of monitoring. (Where applicable, specific mandatory monitoring and techniques may be required.)

(f) Regulated areas. (deleted.)

(f) Regulated areas.

(1) The employer shall establish regulated areas where xxxxx concentrations are in excess of the permissible exposure limits.

(2) Regulated areas shall be demarcated and segregated from the rest of the workplace, in any manner that minimizes the number of persons who will be exposed to xxxxx.

(3) Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the Act or regulations issued pursuant thereto.

(4) The employer shall assure that in the regulated area, food or beverages are not present or consumed, smoking products are not present or used, and cosmetics are not applied, (except that these activities may be conducted in the lunchroom, change rooms and showers required under paragraphs (m)(1) - (m)(3) of this section.)

(f) Regulated areas. (deleted.)

(g) Methods of compliance.

(1) General policy. OSHA 's general policy as to methods of compliance for permanent standards has traditionally required that employee exposures to a substance be reduced to the permissible exposure limits solely by use of engineering and work practice controls. OSHA has permitted reduction of employee exposures by use of respiratory protection only where the employer proves that engineering and work practice controls are not feasible to reduce such exposures to the permissible exposure limits. This general policy is inherent in the model standards found in 29 CFR 1990.160 and 1990.170. However, during the effective period of this emergency temporary standard, OSHA recognizes the need to permit employee exposures to airborne concentrations of xxxxx to be controlled by any practicable combination of engineering controls, work practices and personal protective devices and

(g) Methods of compliance.

(1) Engineering and work practice controls.

(i) The employer shall institute engineering or work practice controls to reduce and maintain employee exposures to xxxxx to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (h) of this section.

(g) Methods of compliance.

(1) Engineering and work practice controls.

(i) The employer shall institute engineering or work practice controls to reduce and maintain employee exposures to xxxxx to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest levels achievable by those controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (h) of this section.

equipment as follows. OSHA recognizes that the immediate reduction of exposure to xxxxx may generally be achieved primarily through the use of respiratory protection and the institution of good work practices during the effective period of this emergency temporary standard, such as the prohibitions against the blowing of dust containing xxxxx or the permitting of open containers and vessels of liquids containing xxxxx. On the other hand, OSHA believes that where engineering or work practice controls can reduce exposure, they should be used, even where such controls by themselves do not reduce the exposures to the permissible exposure limits.

Thus, engineering controls to reduce the airborne concentration of xxxxx shall be instituted, if practicable, as soon as possible. Examples of such controls include substitution of a less hazardous material, enclosure of the process, and use of local exhaust

ventilation systems. The employer should also examine each work area in which xxxxx is present and institute, as soon as possible, work practices to reduce employee exposures to xxxxx to or below the permissible exposure limits. Examples of such work practices include, among other things, limiting access to work areas where xxxxx is present to authorized personnel only; written procedures and work practices for each operation which may result in employee exposure to xxxxx; prohibiting smoking and the consumption of food and beverages in work areas where xxxxx is present; requiring the use of appropriate personal protective clothing and equipment to minimize eye and skin contact with xxxxx; use of signs, labels, or other means to clearly designate all work areas where xxxxx may be present; and institution of good housekeeping practices as set forth in paragraph (k) of this section.

Finally, as pointed out, whenever the engineering and work practice controls described are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer should supplement them by the use of respiratory protection which complies with the requirements of the emergency temporary standard.

(2) Engineering and work practice control plan.

(i) Within ninety (90) days of the effective date of this emergency temporary standard, the employer shall develop a written plan describing proposed means to reduce employee exposures to the lowest feasible level solely by means of engineering and work practice controls (which will be eventually required by a permanent standard for occupational exposure to xxxxx, issued pursuant to section 1990.160 (g) of this subpart).

(ii) Written plans required by this paragraph shall be submitted, upon request, to the Assistant Secretary and the Director and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or designated representative.

(2) Compliance program.

(i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits solely by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to xxxxx;

(B) Engineering plans and other studies used to determine the controls for each process;

(C) A report of the technology considered in meeting the permissible exposure limits;

(2) Compliance program.

(i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits solely by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to xxxxx;

(B) Engineering plans and other studies used to determine the controls for each process;

(C) A report of the technology considered in meeting the permissible exposure limits;

(D) A detailed schedule for the implementation of engineering or work practice controls; and

(E) Other relevant information.

(iii) Written plans for such a program shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or representative.

(iv) The plans required by this paragraph shall be revised and updated at least every six (6) months to reflect the current status of the program.

(D) A detailed schedule for the implementation of engineering or work practice controls; and

(E) Other relevant information.

(iii) Written plans for such a program shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or representative.

(iv) The plans required by this paragraph shall be revised and updated at least every six (6) months to reflect the current status of the program.

(h) Respiratory protection.

(1) Required use. The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposures to within the permissible exposure limits and in emergencies.

(h) Respiratory protection.

(1) General. The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposures to within the permissible exposure limits and in emergencies. Compliance with the permissible exposure limits may not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement feasible engineering and work practice controls; or

(ii) In work operations such as maintenance and repair activities in which the employer establishes that engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(h) Respiratory protection.

(1) General. The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposure to within the permissible exposure limits and in emergencies. Compliance with the permissible exposure limits may not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement feasible engineering and work practice controls; or

(ii) In work operations such as maintenance and repair activities in which the employer establishes that engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(2) Respirator selection.

(i) Where respiratory protection is required or permitted under this section, the employer shall select and provide at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee wears the respirator provided.

Table 1

RESPIRATORY PROTECTION FOR XXXXX

* * *

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to XXXXX).

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(iv) In emergencies.

(2) Respirator selection.

(i) Where respiratory protection is required under this section, the employer shall select and provide at no cost to the employee, the appropriate type of respirator from Table 1 below and shall assure that the employee wears the respirator provided.

Table 1

RESPIRATORY PROTECTION FOR XXXXX

* * *

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to XXXXX).

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(iv) In emergencies.

(2) Respirator selection.

(i) Where respiratory protection is required under this section, the employer shall select and provide at no cost to the employee, the appropriate type of respirator from Table 1 below and shall assure that the employee uses the respirator provided.

Table 1

RESPIRATORY PROTECTION FOR XXXXX

* * *

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to XXXXX).

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) Respirator program.

(i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e) and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator facepiece to prevent potential skin irritation associated with respirator use.

(3) Respirator program.

(i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator facepiece to prevent potential skin irritation associated with respirator use.

(3) Respirator program.

(i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator facepiece to prevent potential skin irritation associated with respirator use.

(i) Emergency situations.

(deleted.)

(i) Emergency situations.

(1) Written plans.

(i) A written plan for emergency situations shall be developed for each workplace where xxxxx is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraph (h) of this section until the emergency is abated.

(2) Alerting employees.

(i) Alarms. Where there is the possibility of employee exposure to xxxxx in excess of the ceiling limit due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(i) Emergency situations.

(1) Written plans.

(i) A written plan for emergency situtations shall be developed for each workplace where xxxxx is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraph (h) of this section until the emergency is abated.

(2) Alerting employees.

(i) Alarms. Where there is the possibility of employee exposure to xxxxx in excess of the ceiling limit due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(ii) Evacuation. Employees not engaged in correcting the emergency shall be restricted from the area and shall not be permitted to return until the emergency is abated.

(ii) Evacuation. Employees not engaged in correcting the emergency shall be restricted from the area and shall not be permitted to return until the emergency is abated.

(j) Protective clothing and equipment.

(1) Provision and use. Where eye or skin contact with xxxxx may occur, the employer shall provide, at no cost to the employee, and assure that employees wear, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and .133 to protect the area of the body which may come in contact with xxxxx.

(2) Cleaning and replacement.

(i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph, as needed, to maintain their effectiveness. In addition the employer shall provide clean protective clothing and equipment at least (insert appropriate time) to each affected employee.

(j) Protective clothing and equipment.

(1) Provision and use. Where eye or skin contact with xxxxx may occur, the employer shall provide at no cost to employee, and assure that employees wear, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and .133 to protect the area of the body which may come in contact with xxxxx.

(2) Cleaning and replacement.

(i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph,

as needed, to maintain their effectiveness. In addition, the employer shall provide clean protective clothing and equipment at least (insert appropriate time) to each affected employee.

(j) Protective clothing and equipment.

(1) Provision and use. Where eye or skin contact with xxxxx may occur, the employer shall provide at no cost to the employee, and assure that employees wear, appropriate protective clothing or equipment in accordance with 29 CFR 1910.132 and .133 to protect the area of the body which may come in contact with xxxxx.

(2) Cleaning and replacement.

(i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph,

as needed, to maintain their effectiveness. In addition the employer shall provide clean protective clothing and equipment at least (insert appropiate time) to each affected employee.

(ii) The employer shall assure that the employee removes all protective clothing and equipment at the completion of a workshift.

(iii) The employer shall assure that xxxxx-contaminated protective clothing and equipment is placed and stored in closed containers which prevent dispersion of xxxxx outside the container.

(ii) The employer shall assure that the employee removes all protective clothing and equipment at the completion of a work shift and only in change rooms as required by paragraph (m)(1) of this section.

(iii) The employer shall assure that xxxxx-contaminated protective clothing and equipment is placed and stored in closed containers which prevent dispersion of xxxxx outside the container.

(iv) The employer shall assure that no employee removes xxxxx-contaminated protective equipment or clothing from the change room, except for those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(ii) The employer shall assure that the employee removes all protective clothing and equipment at the completion of a work shift and only in change rooms as required by paragraph (m)(1) of this section.

(iii) The employer shall assure that xxxxx-contaminated protective clothing and equipment is placed and stored in closed containers which prevent dispersion of xxxxx outside the container.

(iv) The employer shall assure that no employee removes contaminated protective equipment or clothing from the change room except for those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(iv) The employer shall inform any person who launders or cleans xxxxx contaminated protective clothing or equipment of the potentially harmful effects of exposure to xxxxx.

(v) The employer shall assure that the containers of contaminated protective clothing and equipment which are to be removed from the workplace for any reason are labeled in accordance with paragraph (p)(3) of this section.

(vi) The employer shall prohibit the removal of xxxxx from protective clothing or equipment by blowing or shaking.

(v) The employer shall inform any person who launders or cleans xxxxx contaminated protective clothing or equipment of the potentially harmful effects of exposure to xxxxx.

(vi) The employer shall assure that the containers of contaminated protective clothing and equipment which are to be removed from the workplace for any reason are labeled in accordance with paragraph (p)(3) (ii) of this section.

(vii) The employer shall prohibit the removal of xxxxx from protective clothing or equipment by blowing or shaking.

(v) The employer shall inform any person who launders or cleans xxxxx contaminated protective clothing or equipment of the potentially harmful effects of exposure to xxxxx.

(vi) The employer shall assure that the containers of contaminated protective clothing and equipment which are to be removed from the workplace for any reason are labeled in accordance with paragraph (p)(3)(ii) of this section.

(vii) The employer shall probihit the removal of xxxxx from protective clothing or equipment by blowing or shaking of work clothing.

(k) Housekeeping.

(l) Surfaces.

(i) All surfaces shall be maintained free of accumulations of xxxxx.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces where xxxxx dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either portable units or a permanent system may be used.

(A) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that xxxxx is not reintroduced into the work place air; and

(k) Housekeeping.

(l) Surfaces.

(i) All surfaces shall be maintained free of accumulations of xxxxx.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces where xxxxx dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either portable units or a permanent system may be used.

(A) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that xxxxx is not reintroduced into the work place air; and

(k) Housekeeping.

(l) Surfaces.

(i) All surfaces shall be maintained free of accumulations of xxxxx.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces where xxxxx dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either portable units or a permanent system may be used.

(A) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters, or other appropriate means of contaminant removal, so that xxxxx is not reintroduced into the work place air; and

(B) Portable vacuum units used to collect xxxxx, may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (p)(3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) Liquids. Where xxxxx is present in a liquid form, or as a resultant vapor, all containers or vessels containing xxxxx shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(B) Portable vacuum units used to collect xxxxx, may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (p)(3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) Liquids. Where xxxxx is present in a liquid form, or as a resultant vapor, all containers or vessels containing xxxxx shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) Dust collection systems. Periodic cleaning of dust collection systems, i.e. ducts and filters, shall be performed to reduce xxxxx dust buildups and to maintain the effectiveness of the system.

(B) Portable vacuum units used to collect xxxxx, may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (p) (3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) Liquids. Where xxxxx is present in a liquid form, or as a resultant vapor, all containers or vessels containing xxxxx shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) Dust collection systems. Periodic cleaning of dust collection systems, i.e. ducts and filters, shall be performed to reduce xxxxx dust buildups and to maintain the effectiveness of the system.

(1) Waste disposal. xxxxx waste, scrap, debris, bags, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of xxxxx outside the container.

(1) Waste disposal. xxxxx waste, scrap, debris, bags, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of xxxxx outside the container.

(1) Waste disposal. xxxxx waste, scrap, debris, bags, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of xxxxx outside the container.

(m) Hygiene facilities and practices. Where employees are exposed to airborne concentrations of xxxxx, or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the facilities required by 29 CFR 1910.141 shall be provided by the employer for the use of those employees, and the employer shall assure that the employees use the facilities provided.

(m)

Hygiene facilities and practices. Where employees are exposed to airborne concentrations of xxxxx, or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the facilities required by 29 CFR 1910.141 shall be provided by the employer for the use of those employees and the employer shall assure that the employees use the facilities provided. In addition, the following additional facilities or requiments are mandated.

(1) Change rooms. The employer shall provide clean change rooms in accordance with 29 CFR 1910.141(e).

(2) Showers.

(i) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(m)

Hygiene facilities and practices. Where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the facilities required by 29 CFR 1910.141 or in this paragraph shall be provided by the employer for the use of those employees and the employer shall assure that the employees use the facilities provided. In addition, the following additional facilities or requirements are mandated.

(1) Change rooms. The employer shall provide clean change rooms in accordance with 29 CFR 1910.141(e).

(2) Showers.

(i) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(ii) In addition, the employer shall also assure that employees exposed to XXXXX shower at the end of the work shift.

(3) Lunchrooms.

(i) Whenever food or beverages are consumed in the workplace, the employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees exposed to XXXXX.

(ii) In addition the employer shall also assure that employees exposed to XXXXX wash their hands and face prior to eating.

(ii) In addition, the employer shall also assure that employees exposed to XXXXX shower at the end of the work shift.

(3) Lunchrooms.

(i) The employer shall provide appropriate facilities for eating and drinking in accordance with 29 CFR 1910.141 (g) and (h).

(ii) The employer shall assure that employees exposed to XXXXX wash their hands and face prior to eating.

(n) Medical surveillance.

(1) General.

(i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to XXXXX. The employee shall provide each such employer with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(n) Medical Surveillance.

(1) General.

(i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to XXXXX. The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(n) Medical Surveillance.

(1) General.

(i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to XXXXX. The employer shall provide each employee with an apportunity for medical examinations and tests in accordance with this paragrpah.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) Initial examinations. Within thirty (30) days of the effective date of this section, or thereafter at the time of initial assignment, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history, a medical history, and a physical examination with direct emphasis towards the pulmonary, renal, and hepatic systems, and shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors. Additionally, such factors as the current systems review, pregnancy, current treatment with steroids or cytotoxic agents, and smoking habits should be considered.

(ii) The medical examination shall also include the following: (insert appropriate medical protocol).

(2) Initial examinations. At the time of initial assignment, or upon institution of the medical surveillance program, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history, a medical history, and a physical examination with direct emphasis towards the pulmonary, renal and hepatic systems, and shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors. Additionally, such factors as the current systems review, pregnancy, current treatment with steroids or cytotoxic agents, and smoking habits should be considered.

(ii) The medical examination shall also include the following: (insert appropriate medical protocol).

(2) Initial examinations. At the time of initial assignment, or upon institution of the medical surveillance program, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history, a medical history, and a physical examination with direct emphasis towards the pulmonary, renal and hepatic systems, and shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors. Additionally, such factors as the current systems review, pregnancy, current treatment with steroids or cytotoxic agents, and smoking habits should be considered.

(ii) The medical examination shall also include the following: (insert appropriate medical protocol).

(3) Periodic examinations. (Insert appropriate medical protocol and time.)

(4) Interim examinations. If the employee for any reason develops signs or symptoms commonly associated with exposure to xxxxx, the employer shall provide appropriate examination and emergency medical treatment.

(3) Periodic examinations.

(i) The employer shall provide examinations specified in this paragraph at least (insert appropriate time) for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examinations prescribed in paragraph (n)(2) of this section within 6 months of termination of employment, the employer shall make such examination available to the employee upon such termination.

(4) Additional examinations. If the employee for any reason develops signs or symptoms commonly associated with exposure to xxxxx, the employer shall provide appropriate examination and emergency medical treatment.

(3) Periodic examinations.

(i) The employer shall provide examinations specified in this paragraph at least (insert appropriate time) for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examinations prescribed in paragraph (n)(2) of this section within 6 months of termination of employment, the employer shall make such examination available to the employee upon such termination.

(4) Additional examinations. If the employee for any reason develops signs or symptoms commonly associated with exposure to xxxxx, the employer shall provide appropriate examination and emergency medical treatment.

(5) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this emergency temporary standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level; and

(iv) A description of any personal protective equipment used or to be used.

(5) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) Information from previous medical examinations of the affected employee, which is not otherwise available to the examining physician.

(5) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure:

(iii) The employee's representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) Information from previous medical examinations of the affected employee, which is not otherwise available to the examining physician.

(6) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to xxxxx;

(C) Any recommended limitations upon the employee's exposure to xxxxx or upon the use of protective clothing and equipment such as respirators; and

(6) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to xxxxx;

(C) Any recommended limitations upon the employee's exposure to xxxxx or upon the use of protective clothing and equipment such as respirators; and

(6) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to xxxxx.

(C) Any recommended limitations upon the employee's exposure to xxxxx or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to xxxxx;

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to xxxxx;

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to xxxxx.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) Employee information and training.

(1) Training program.

(i) Within thirty (30) days from the effective date of this standard, the employer shall institute a training program for all employees where there is occupational exposure to xxxxx and shall assure their participation in the training program.

(ii) The employer shall assure that each employee is informed of the following:

(A) The information contained in Appendices A, B and C;

(o) Employee Information and Training.

(1) Training Program.

(i) The employer shall institute a training program for all employees where there is occupational exposure to xxxxx and shall assure their participation in the training program.

(ii) The training program shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter, and the employer shall assure that each employee is informed of the following:

(A) The information contained in Appendices A, B and C;

(o) Employee information and training.

(1) Training program.

(i) The employer shall institute a training program for all employees where there is occupational exposure to xxxxx and shall assure their participation in the training program.

(ii) The training program shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter, and the employer shall assure that each employee is informed of the following:

(A) The information contained in Appendices A, B and C;

(B) The quantity, location, manner of use, release or storage of xxxxx and the specific nature of operations which could result in exposure to xxxxx, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators;

(D) The purpose and description of the medical surveillance program required by paragraph (n) of this section; and

(E) A review of this standard.

(B) The quantity, location, manner of use, release or storage of xxxxx and the specific nature of operations which could result in exposure to xxxxx, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of the respirators;

(D) The purpose and a description of the medical surveillance program required by paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section; and

(F) The engineering and work practice controls, their function and the employee's relationship thereto; and

(G) A review of this standard.

(B) The quantity, location, manner of use, release or storage of xxxxx and the specific nature of operations which could result in exposure to xxxxx, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators;

(D) The purpose and a description of the medical surveillance program required by paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section;

(F) The engineering and work practice controls, their function and the employee's relationship thereto; and

(G) A review of this standard.

(2) Access to training materials.

(i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(2) Access to Training Materials.

(i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(2) Access to training materials.

(i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) Signs and labels.

(1) General.

(i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from such effects of the required sign or label.

(2) Signs.

(i) The employer shall post signs to clearly indicate all workplaces where XXXXX may be present. The signs shall bear the following legend:

DANGER

XXXXX

(Insert appropriate trade or common names)

CANCER HAZARD

AUTHORIZED PERSONS ONLY

(p) Signs and Labels.

(1) General.

(i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from such effects of the required sign or label.

(2) Signs.

(i) The employer shall post signs to clearly indicate all workplaces where XXXXX may be present. The signs shall bear the following legend:

DANGER

XXXXX

(insert appropriate trade or common names)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(p) Signs and labels.

(1) General.

(i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from the effects of such required sign or label.

(2) Signs.

(i) The employer shall post signs to clearly indicate all work areas where XXXXX may be present. The signs shall bear the following legend:

CAUTION

XXXXX

(insert appropriate trade or common names)

POTENTIAL CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Where airborne concentrations of XXXXX exceed the permissible exposure limits, the signs shall bear the additional legend: "Respirators Required"

(3) Labels.

(i) The employer shall assure that precautionary labels are affixed to all containers of XXXXX and of products containing XXXXX, and that the labels remain affixed when the XXXXX or products containing XXXXX are sold, distributed or otherwise leave the employer's workplace.

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Where airborne concentrations of XXXXX exceed the permissible exposure limits, the signs shall bear the additional legend: "Respirator Required"

(3) Labels.

(i) The employer shall assure that precautionary labels are affixed to all containers of XXXXX and of products containing XXXXX, and that the labels remain affixed when the XXXXX or products containing XXXXX are sold, distributed or otherwise leave the employer's workplace.

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readibly visible.

(iii) Where airborne concentrations of XXXXX exceed the permissible exposure limits, the signs shall bear the additional legend:

"Respirator Required"

(3) Labels. The employer shall assure that precautionary labels are affixed to all containers of XXXXX and of products containing XXXXX and that the labels remain affixed when the XXXXX or products containing XXXXX are sold, distributed or otherwise leave the employer's workplace. The label shall bear the following legend:

CAUTION

CONTAINS XXXXX

POTENTIAL CANCER HAZARD

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS XXXXX

CANCER HAZARD

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS XXXXX

CANCER HAZARD

(q) Recordkeeping.

(1) Exposure monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(q) Recordkeeping.

(1) Exposure Monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(q) Recordkeeping.

(1) Exposure monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for the effective period of this emergency temporary standard, and for any additional period required by the permanent standard.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions;

(B) Any employee medical complaints related to exposure to xxxxx;

(C) A copy of the information provided to the physician as required by paragraph (n) (6) of this section; and

(D) A copy of the employee's work history.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) Medical Surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions;

(B) Any employee medical complaints related to exposure to xxxxx;

(C) A copy of the information provided to the physician as required by paragraph (n) (6) of this section; and

(D) A copy of the employee's work history.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions;

(B) Any employee medical complaints related to exposure to xxxxx;

(C) A copy of the information provided to the physician as required by paragraph (n) (6) of this section; and

(D) A copy of the employee's work history.

(iii) The employer shall assure that this record be maintained for the effective period of this emergency temporary standard, and for any additional period required by the permanent standard.

(3) Availability.

(i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records, as required by this section, be made available, upon request, for examination and copying to the affected employee, former employee, or designated representative.

(iii) The employer shall assure that this record be maintained for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(3) Availability.

(i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records, as required by this section, be made available, upon request, for examination and copying to the affected employee, former employee, or designated representative.

(iii) The employer shall assure that this record be maintained for at least forth (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(3) Availability.

(i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure measurement records, as required by this section, be made available, upon request, for examination and copying, to the affected employee, former employee, or designated representative.

(iii) The employer shall assure that employee medical records required to be maintained by this section, be made available, upon request, for examination and copying to the affected employee or former employee, or to a physician designated by the affected employee, former employee, or designated representative.

(iii) The employer shall assure that employee medical records required to be maintained by this section, be made available, upon request, for examination and copying, to the affected employee or former employee, or to a physician designated by the affected employee, former employee, or designated representative.

(4) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) The employer shall assure that employee medical records required to be maintained by this section, be made available, upon request, for examination and copying to the affected employee or former employee, or to a physician designated by the affected employee, former employee, or designated representative.

(4) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained pursuant to this section, the employer shall transmit these records to the Director.

(iii) At the expiration of the retention period for the records required to be maintained pursuant to this section, the employer shall transmit these records to the Director.

(r) Observation of monitoring.

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to XXXXX conducted pursuant to paragraph (e) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to XXXXX requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(r) Observation of Monitoring.

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to XXXXX conducted pursuant to paragraph (e) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to XXXXX requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(r) Observation of monitoring.

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to XXXXX conducted pursuant to paragraph (e) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to XXXXX requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of XXXXX performed at the place of exposure; and

(C) Record the results obtained.

(ii) Without interfering with the monitoring observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of XXXXX performed at the place of exposure; and

(C) Record the results obtained.

(ii) Without interfering with the monitoring observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of XXXXX performed at the place of exposure; and

(C) Record the results obtained.

(s) Effective date. This section shall become effective (insert date of publication).

(t) Appendices. The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A

SUBSTANCE SAFETY DATA SHEET

XXXXX

Appendix B

SUBSTANCE TECHNICAL GUIDELINES

XXXXX

Appendix C

MEDICAL SURVEILLANCE GUIDELINES

XXXXX

(s) Effective date. This section shall become effective (insert appropriate period) following publication.

(t) Appendices. The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A

SUBSTANCE SAFETY DATA SHEET

XXXXX

Appendix B

SUBSTANCE TECHNICAL GUIDELINES

XXXXX

Appendix C

MEDICAL SURVEILLANCE GUIDELINES

XXXXX

(s) Effective dates. This section shall become effective (insert appropriate period) following publication .

(t) Appendices. The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A

SUBSTANCE SAFETY DATA SHEET

XXXXX

Appendix B

SUBSTANCE TECHNICAL GUIDELINES

XXXXX

Appendix C

MEDICAL SURVEILLANCE GUIDELINES

XXXXX

Advance Orders are now being Accepted
for delivery in about 6 weeks

CODE OF FEDERAL REGULATIONS

(Revised as of April 1, 1977)

Quantity	Volume	Price	Amount
_____	Title 25—Indians	$4.50	$_____
_____	Title 26—Internal Revenue (Part 1, §§ 1.0–1.169)	4.75	_____
_____	Title 26—Internal Revenue (Parts 2–29)	4.50	_____
		Total Order	$_____

[A Cumulative checklist of CFR issuances for 1977 appears in the first issue of the Federal Register each month under Title 1]

PLEASE DO NOT DETACH

MAIL ORDER FORM To:
Superintendent of Documents, Government Printing Office, Washington, D.C. 20402

Enclosed find $..... (check or money order) or charge to my Deposit Account No. .....

Please send me ..... copies of:

PLEASE FILL IN MAILING LABEL BELOW

Name .....
Street address .....
City and State ..... ZIP Code .....

FOR USE OF SUPT. DOCS.
Enclosed
To be mailed later
Subscription
Refund
Postage
Foreign Handling

FOR PROMPT SHIPMENT, PLEASE **PRINT OR TYPE** ADDRESS ON LABEL BELOW, INCLUDING **YOUR ZIP CODE**

SUPERINTENDENT OF DOCUMENTS
U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON, D.C. 20402

OFFICIAL BUSINESS

POSTAGE AND FEES PAID
U.S. GOVERNMENT PRINTING OFFICE
375
SPECIAL FOURTH-CLASS RATE BOOK

Name .....
Street address .....
City and State ..... ZIP Code .....